(12) UK Patent Application (19) GB (11) 2 307 860 (13) A

(43) Date of A Publication 11.06.1997

- (21) Application No 9525074.2
- (22) Date of Filing 07.12.1995
- (71) Applicant(s) Wolfgang Wagner Schaufterpfad 46, 13503 Berlin,

Federal Republic of Germany

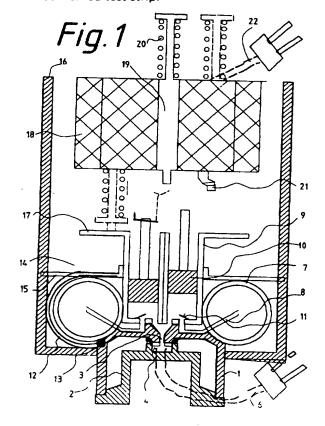
- (72) Inventor(s) Wolfgang Wagner
- (74) Agent and/or Address for Service Chris Jephcott 39 Eversly Crescent, Winchmore Hill, London, N 21, **United Kingdom**

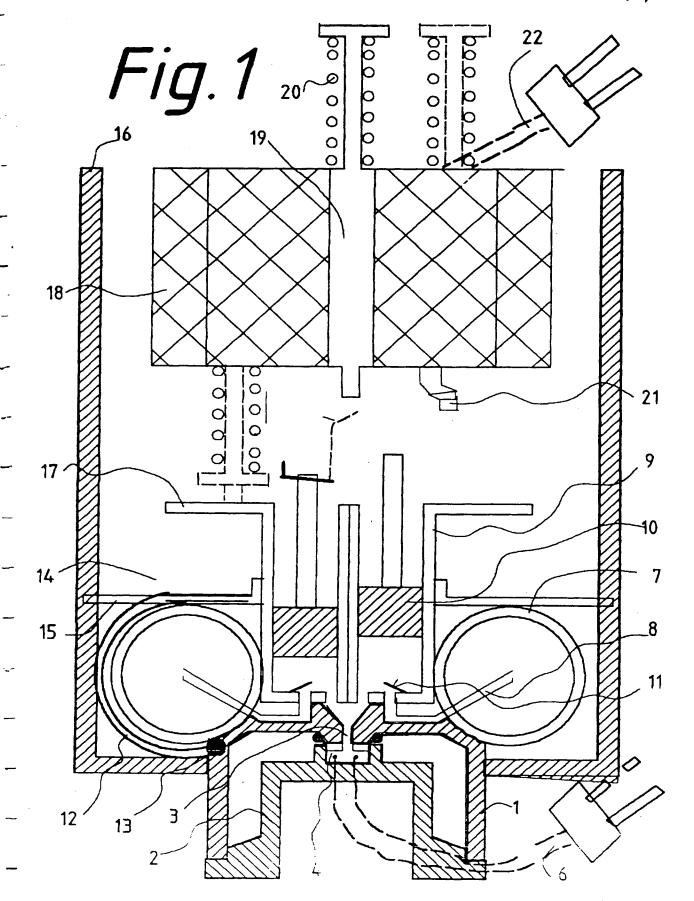
- (51) INT CL6 A61M 5/30, G01N 33/48
- (52) UK CL (Edition O) **A5R** RCJ G1B BCE
- (56) Documents Cited None
- (58) Field of Search UK CL (Edition O) A5R RCJ INT CL6 A61M 5/30 5/315 **ONLINE: WPI**

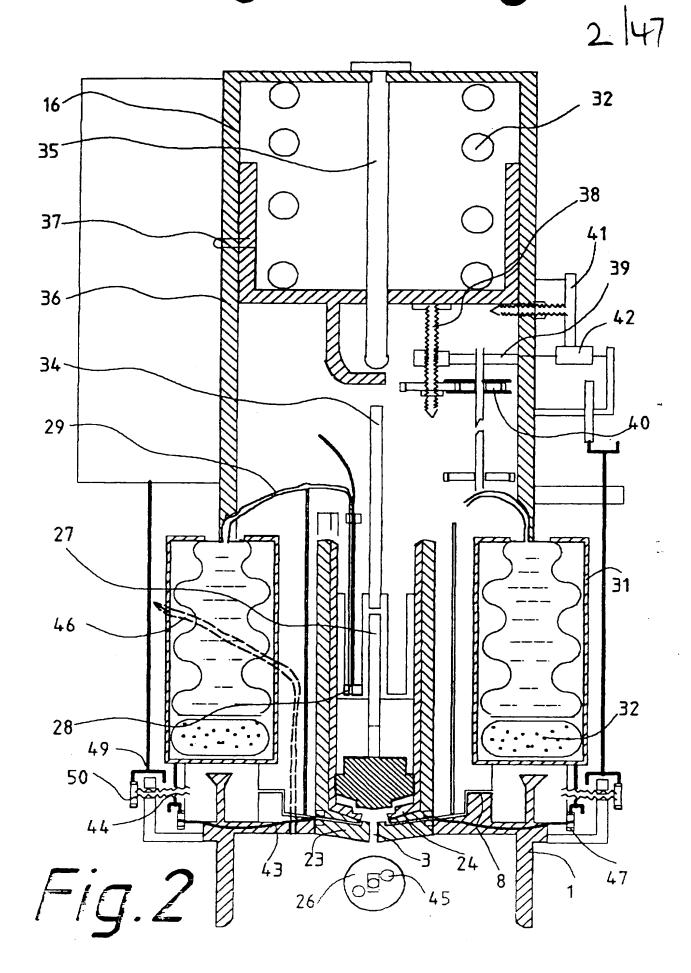
(54) Device for monitoring and treating diabetes

A device for the treatment of diabetics using jet injection includes a suction cup (1) for raising the skin and separate sources of insulin and cleansing fluid (7) eg saline solution. In use, the injection channel (3) is rinsed with the cleansing fluid during the insulin injection to even out the injection pressure and so prevent suck-back of air into the insulin syringe because of the suction vacuum.

Also claimed is (1) a system (not shown) for measuring the metabolism eg blood sugar which includes a sensor which punctures the skin and transmits signals indicative of the metabolism to electronic control means and (2) a urine collector and combined test strip.







BNSDOCID: <@B___2307860A__L>

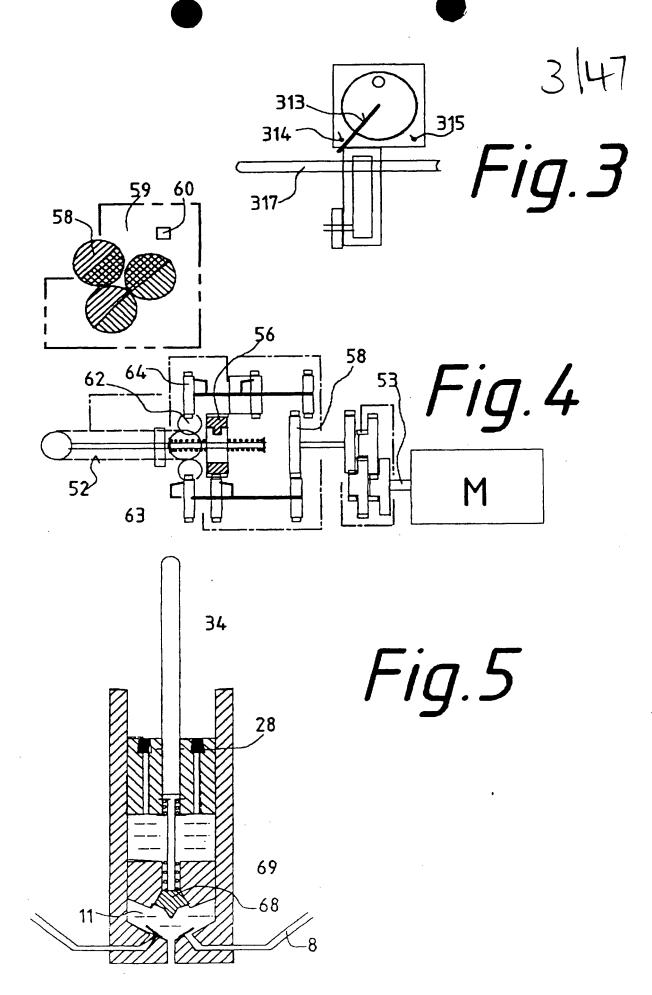


Fig.6

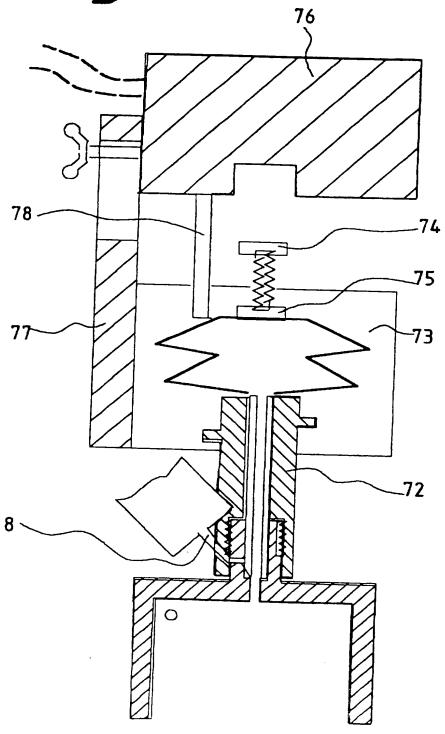
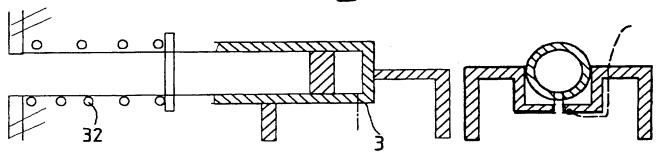
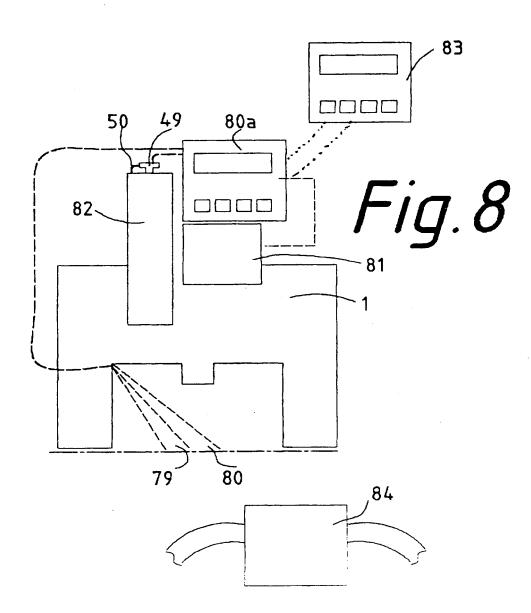
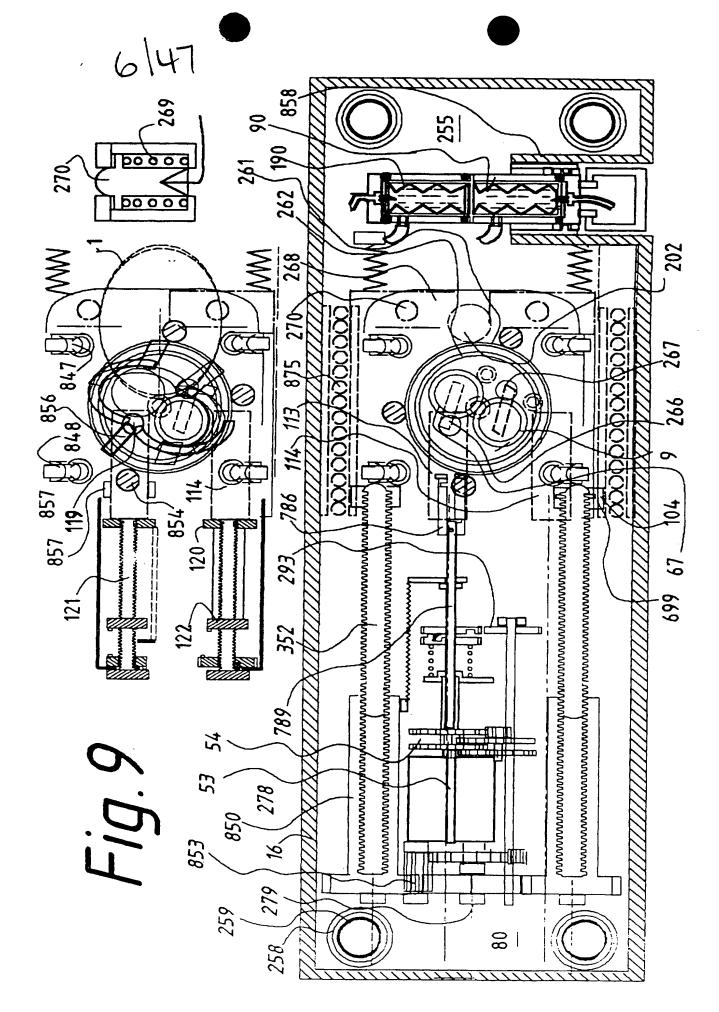
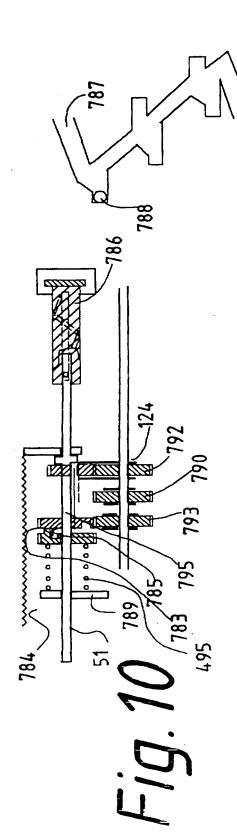


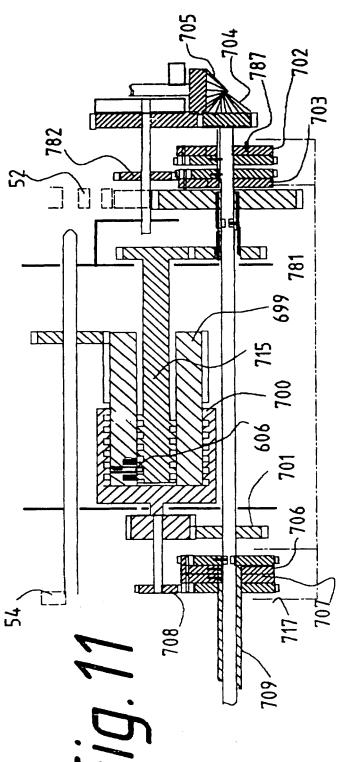
Fig. 7

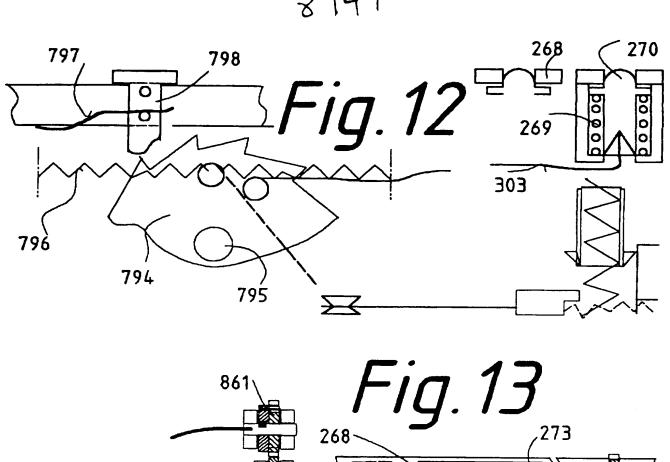


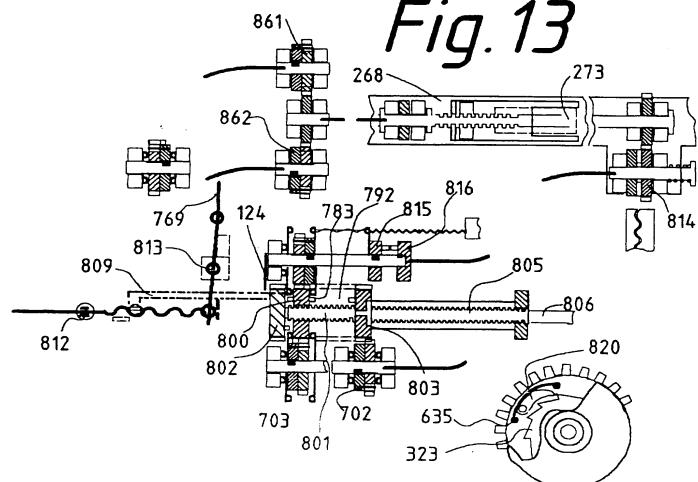


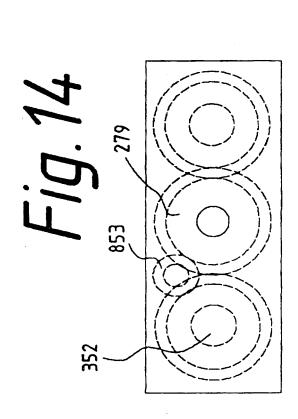


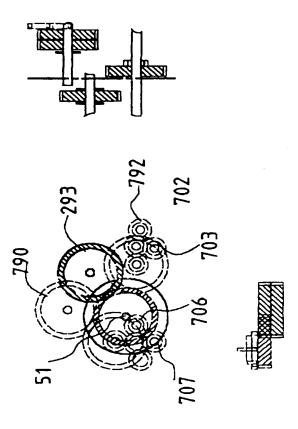


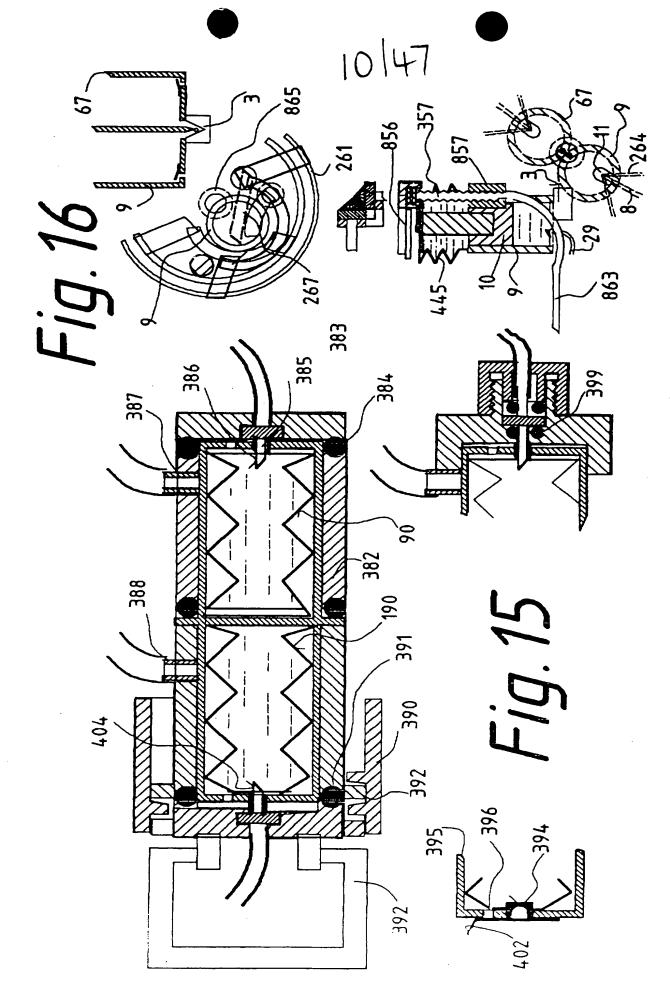


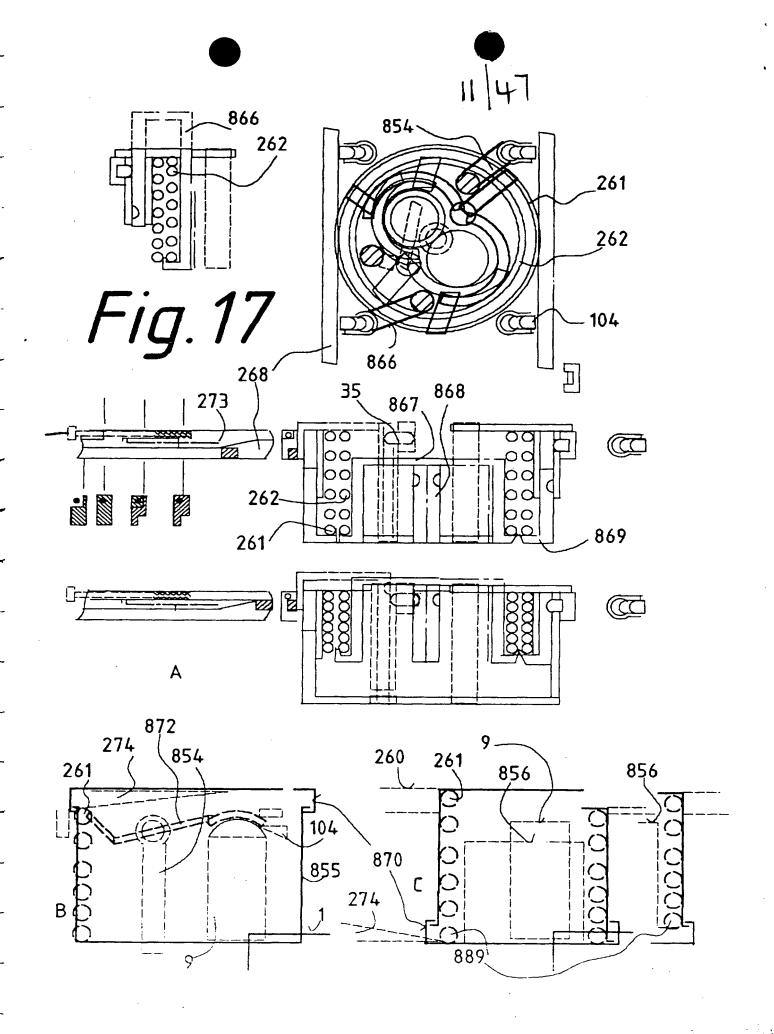












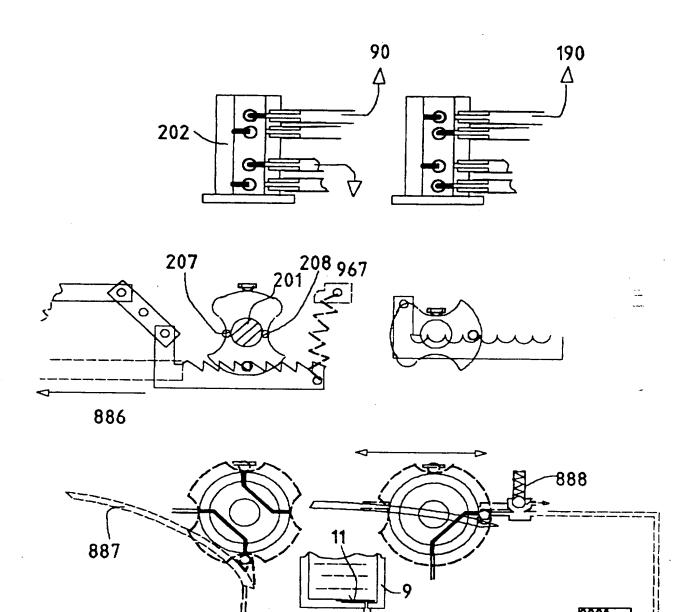
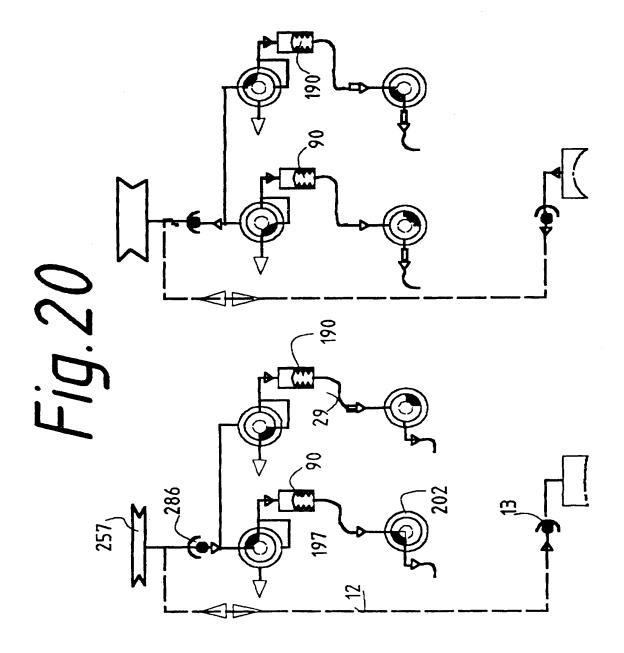
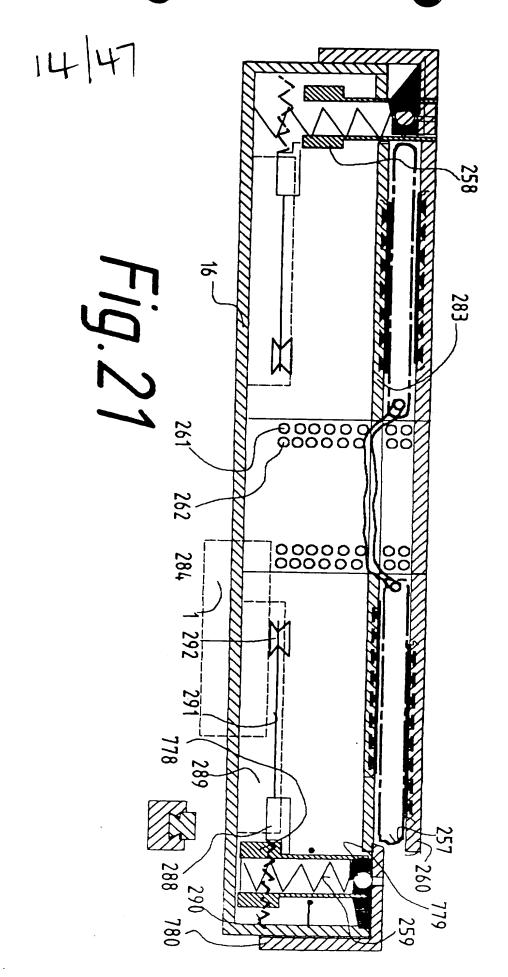


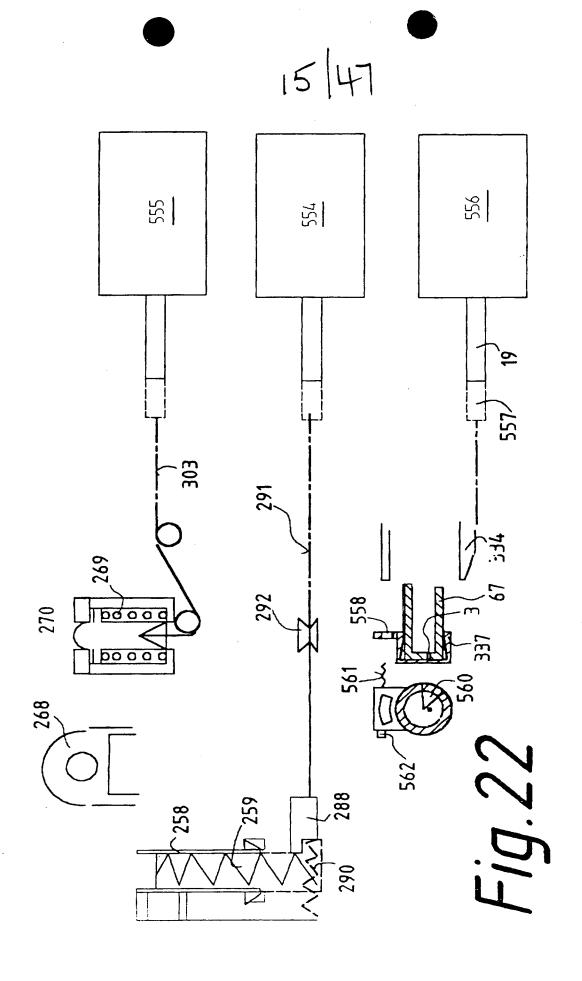
Fig. 19

90

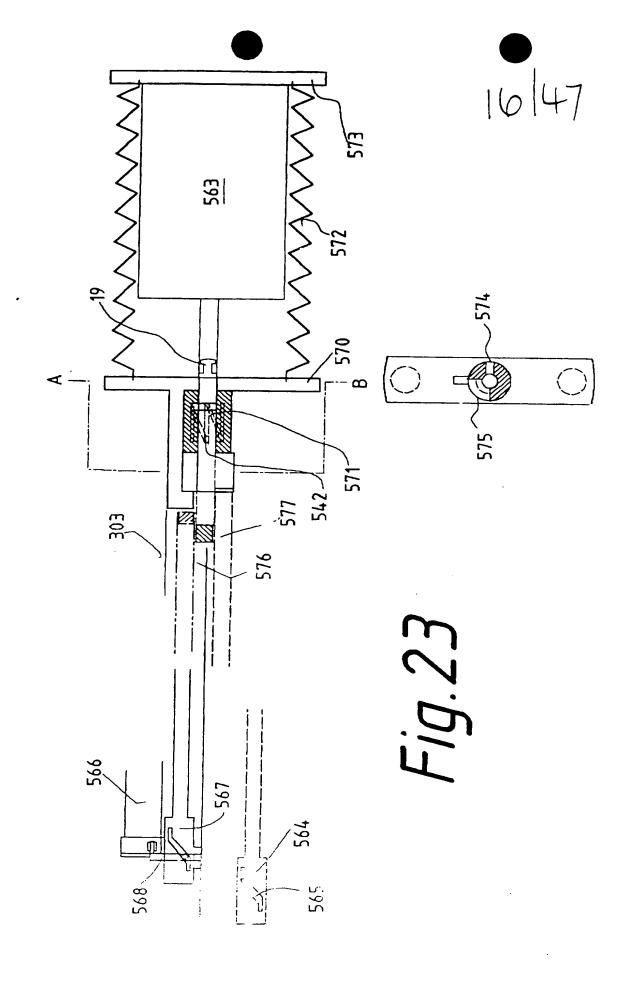


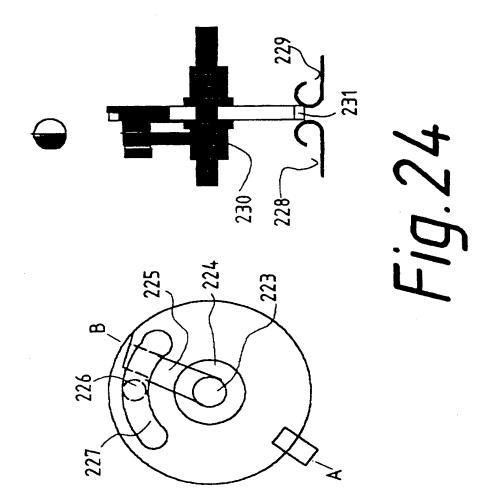


BNSDOCID: <GB__2307960A__L>

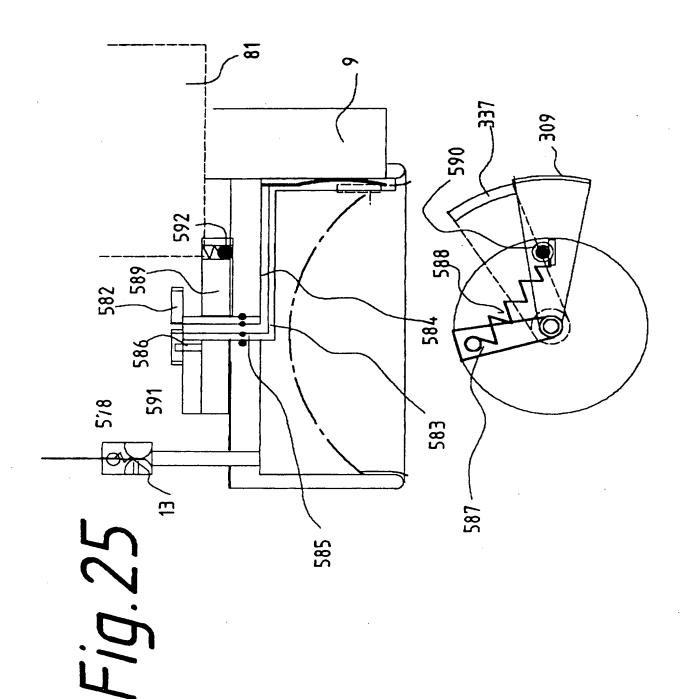


BNSDOCID: <GB__2307960A__L>

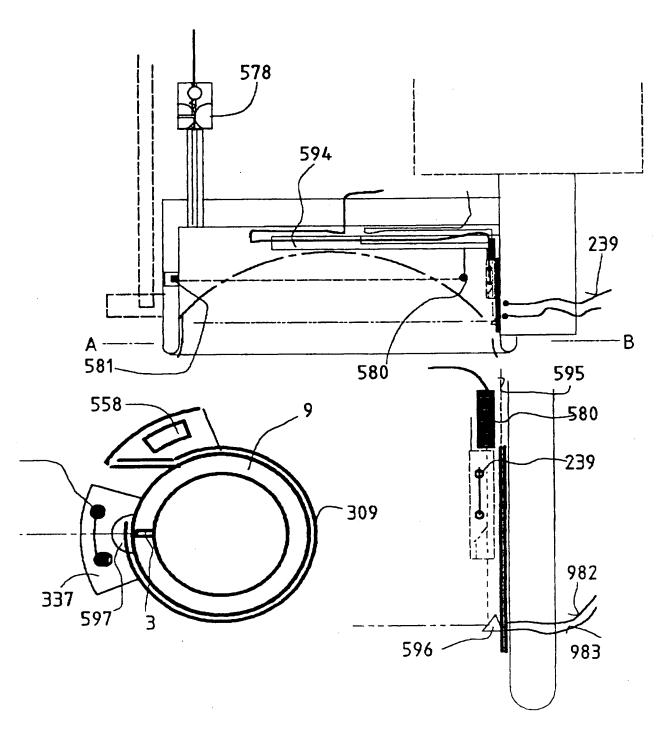




18 | 47

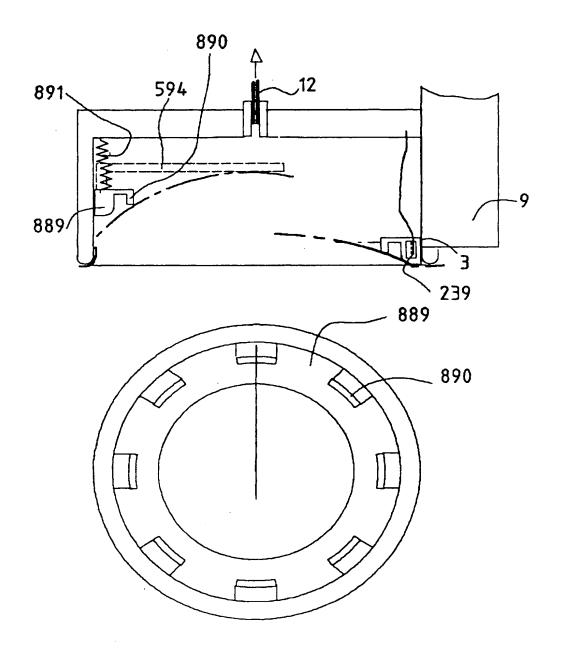


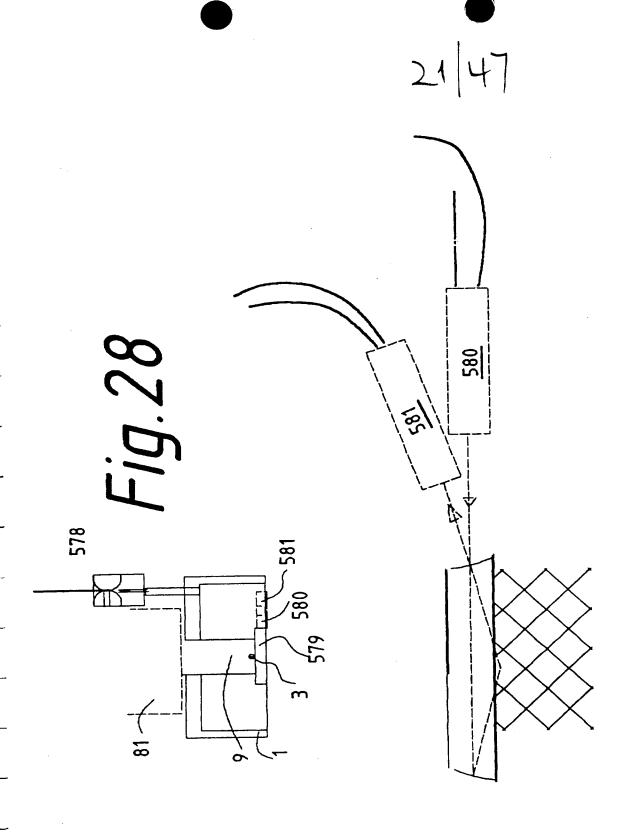
19/47 Fig. 26

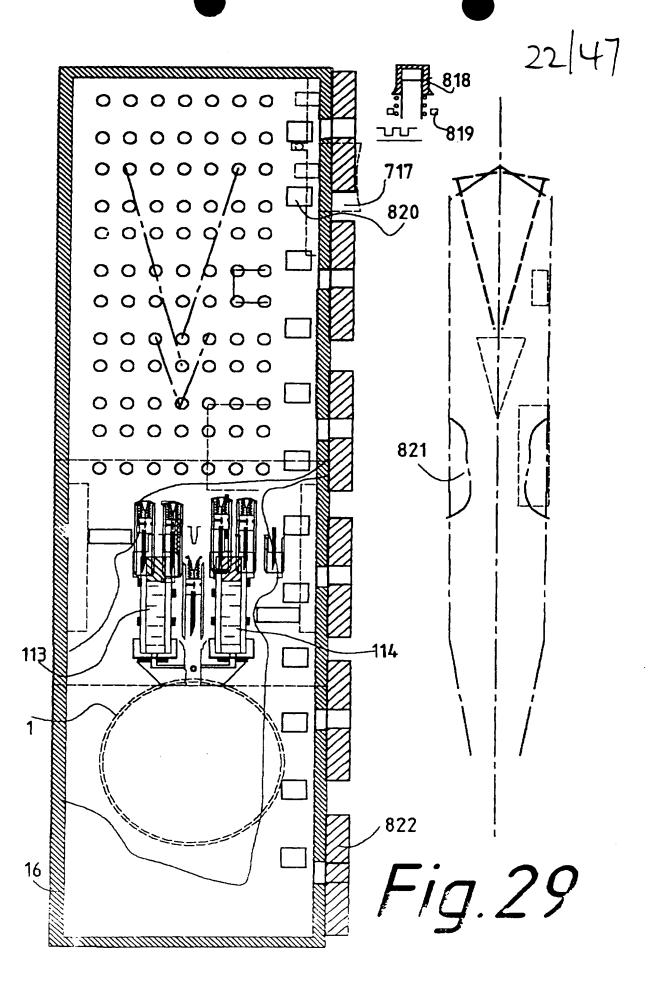


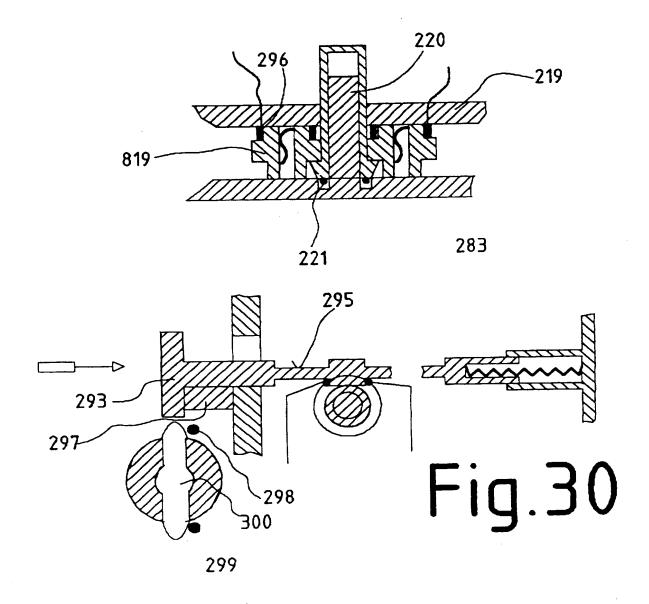
20 47

Fig.27

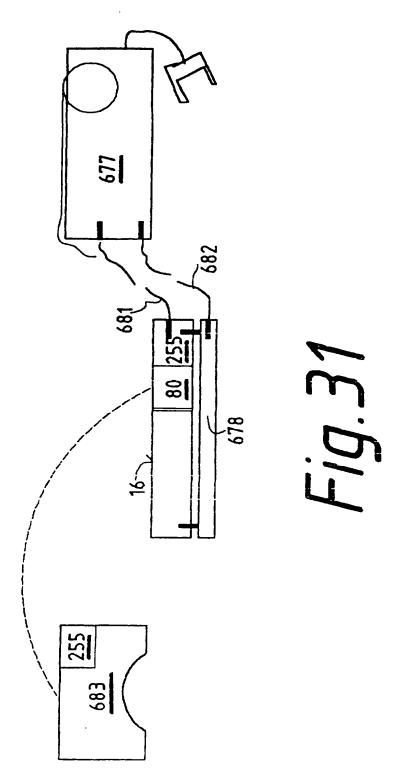


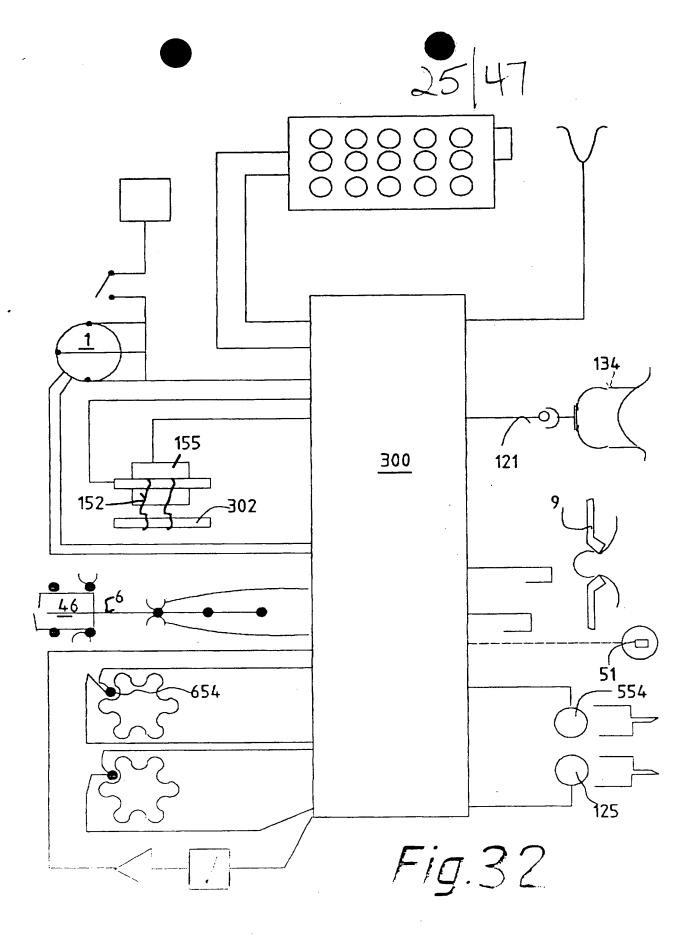


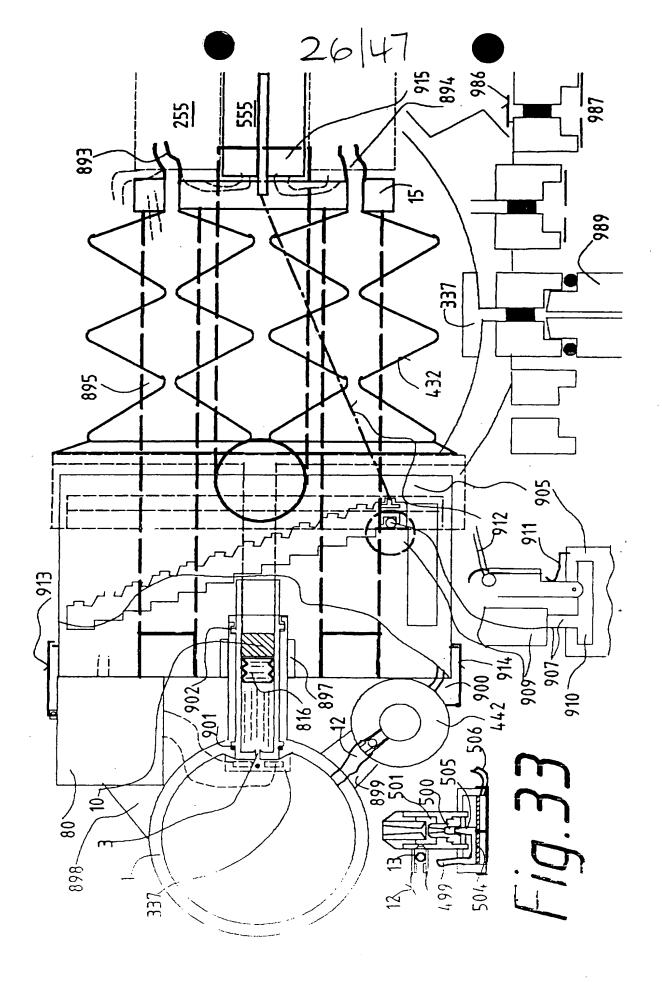




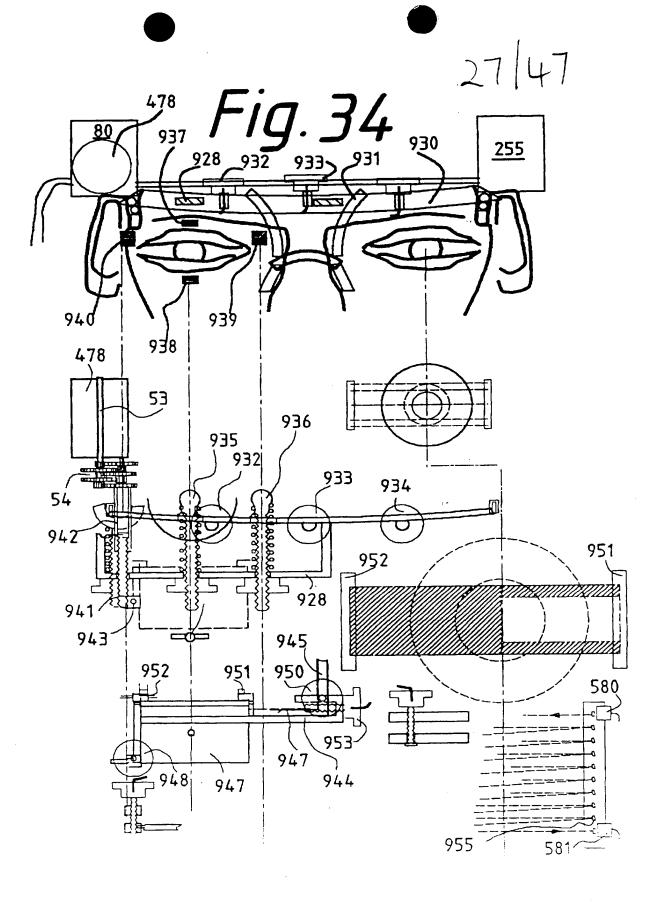
24/47

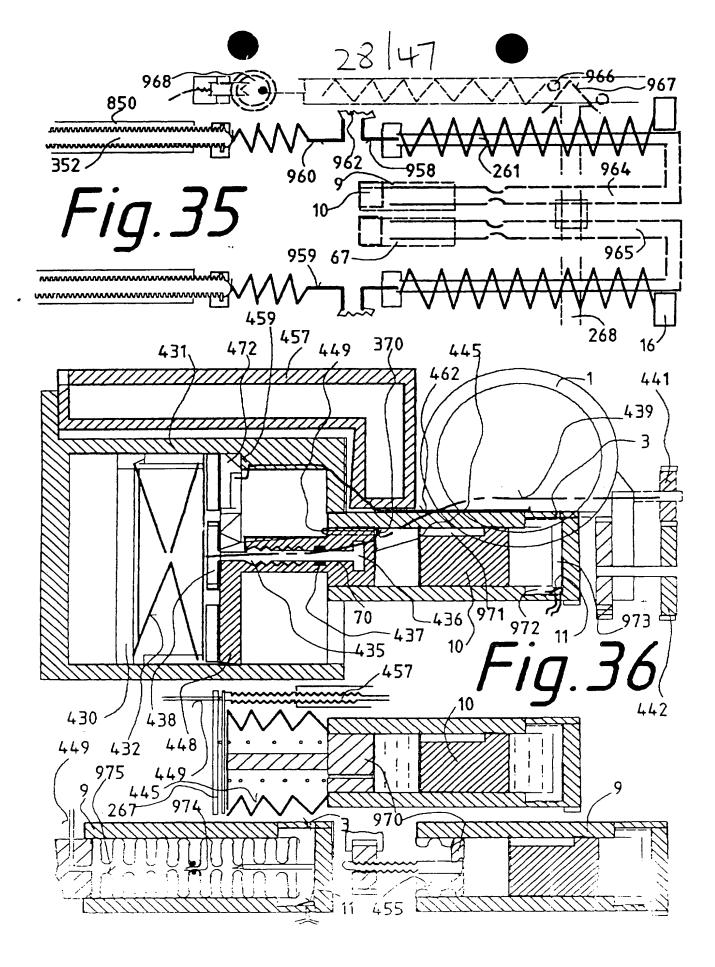


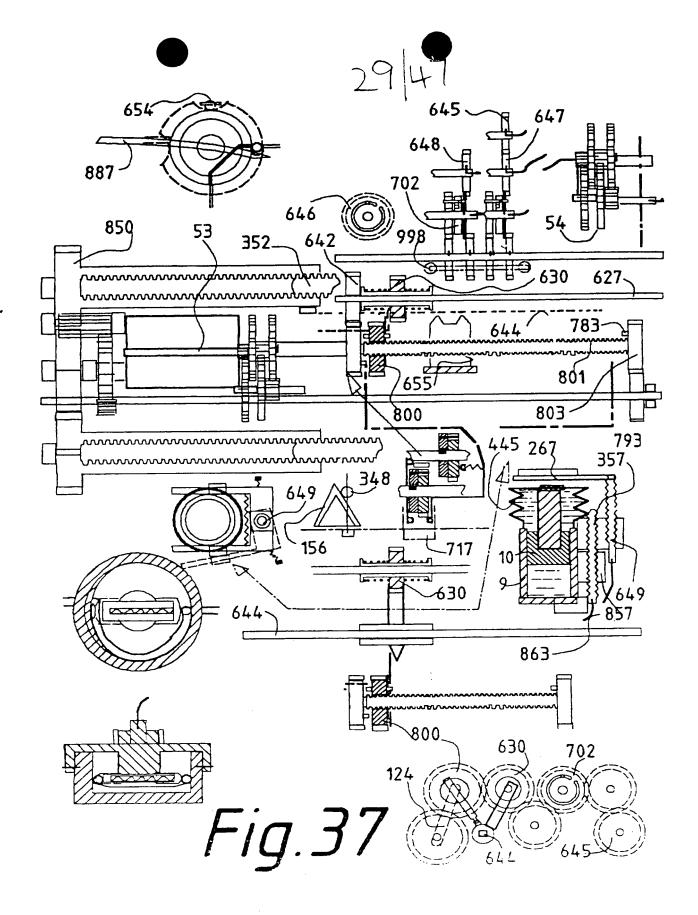


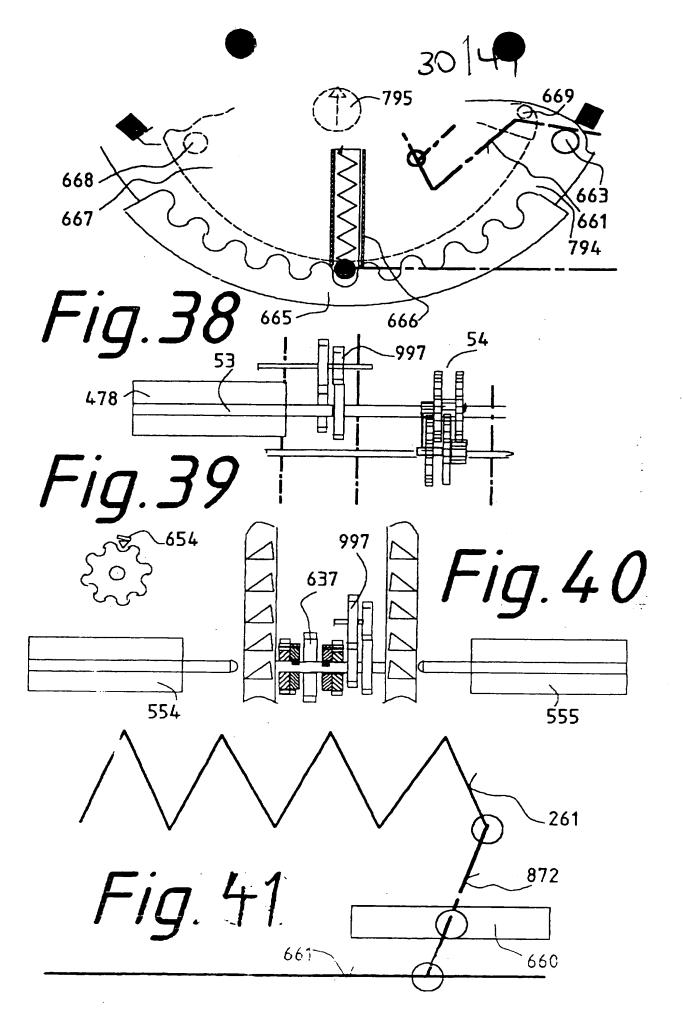


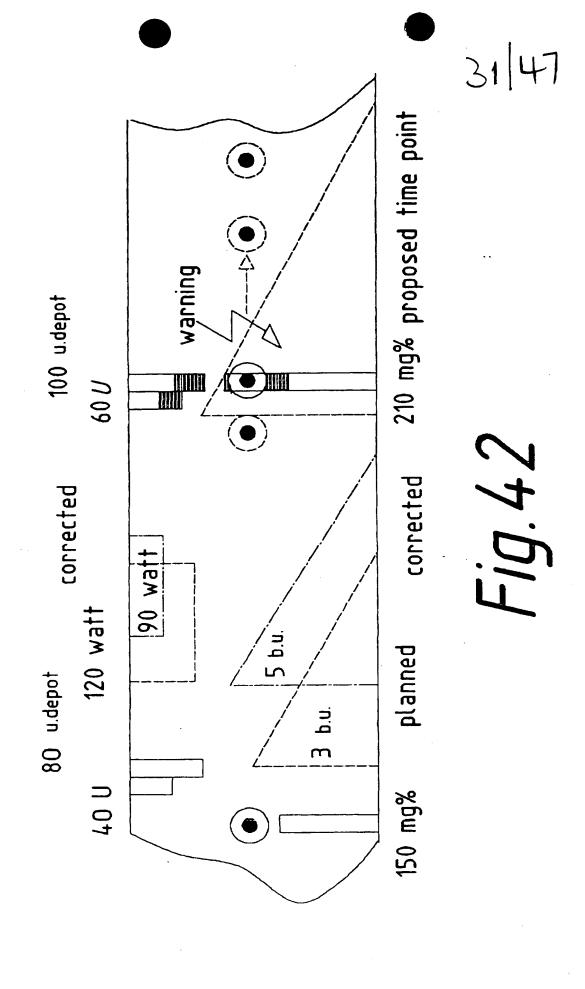
BNSDOCID: <GB___2307960A__i_>











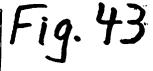
BNSDOCID: <GB___2307860A__L;

A schematic calculation of necessary Insulin quantities based on sample input data of food consumption and working power from a fictive diabetic

INFO PAGE PAGE A

RANGE NAMES

BSL_OHL1	CALC:C11C60	NEW_BSL	INPUT:P11P60
BSL_OHL2	CALC:H11H60	PRT_CALC	CALC:A1N54
BSL_OHL3	CALC:L11L60	PRT_INFO	INFO:A1G40
BV_BSL	INPUT:B11B60	PRT_INPUT	INPUT:A1P54
FC1	INPUT:D14D20	TIME	INPUT:A11A60
FC2	INPUT:G18G24	וסט	CALC:111160
FC3	INPUT:J26J32	UDI_EFFECT	CALC:J11J60
FC4	INPUT:G38G44	URI	CALC:D11D60
FV_BSL	CALC:K11K60	URI_EFFECT	CALC:E11E60
MV BSL	CALC:F11F60	WP	INPUT:M11M60



Abbreviations used on page B and C:

BSL = blood sugar level

WP = working power

B = beginn of working time

URI = injection of some units regular Insulin HL = high limit of BSL UDI = injection of some units depot Insulin

FC = food consumption changes of $BSL = \pm BSL$

E = end of working time

LL = low limit of BSL

Basic formulas used for changes of BSL:

increasing BSL caused by food consumption = 20mg% * FC during 0.5 hours decreasing BSL after FC+0.5 hours = 20mg% * FC, equally distributed over 3 hours

working power WP [W=Watt] during working time T [h=hour] reducing BSL (increasing effect) caused by working = 20mg% * T * WP/50 reducing BSL (decreasing effect) after work is finished = 20mg% * T * WP/50

reducing BSL through injection of regular Insulin after 0.5 hours delay = 4mg% * URI during 0.5 hours decreasing effect after 1 hour = 4mg% * URI, equally distributed over 2 hours

reducing BSL through injection of depot Insulin after 2 hours delay = 2mg% * UDI during 3 hours decreasing effect after 5 hours = 2mg% * UDI, equally distributed over 12 hours

A schematic calculation of necessary Insulin quantities based on sample input data of food consumption and working power from a fictive diabetic INPUT DATA

PAGE B INPUT												T	DATA			
	Fig). TT								WP						
	•		FC			FC		ــــــــا	FC							BV
base va	lue (BV)	+	3	BU	+	1	BU	+	6	BU	50	W C	luring		- 4	
of BSL with		@	1	h	@	3	h	@	7	h				8		and FC
decreasing effect		+	0	BU	+	5	BU	+	0	BU	0	W c	luring			and WP
of depot Insulin		@	0	h	@	13	h	@	0	h				0	h	= NEW
time[h]	BV[mg%]		BSLIr		+	BSUn	ng%]	±1	BSUn	ng%l		±BS	Umg%	<u>()</u>		BSUmg%l
0.0	100	-			-		Ω								\Box	100
0.5	103	-						1							4	103
1.0	107	FC			 			T							4	107
1.5	110	-	60								<u> </u>				4	170
2.0	113	1	50												-#	163
2.5	117		40								ļ				#	157
3.0	120	T-	30		FC						<u> </u>				-	150 163
3.5	123		20			20					ļ				-	153
4.0	127		10			17					↓				-	143
4.5	130		0			13				· ·	↓				-	143
5.0	133					10		1			<u> </u>					143
5.5	137					7		↓			ļ					143
6.0	140	1				3		 								143
6.5	143				<u> </u>	-0		1=0							#	147
7.0	147				 			FC	120		┼				-+	270
7.5	150	<u> </u>			ļ				100				0		В	253
8.0	153	↓						-	80		-		-10		-	227
8.5	157	<u> </u>			ļ			-	60				-20			200
9.0	160	 			 				40		+		-30			173
9.5	163	₩							20		 		-40		E	147
10.0	167								-0		+		-30			140
10.5	170	1			+			+			+		-20			153
11.0	173	#			+						+		-10			167
11.5	177	#						-			+		0		_	180
12.0	180	#			+			+			+					183
12.5	183	#-			FC											187
13.0	187	-			 : 	100)	_			1			-		290
13.5	190	#-			+-	83					+					277
1. 0	193 197	-				67		1								263
14	200	+-			+-	50		\neg			1					250
15	200				+	33					1-					237
15 5	4	ii.			 -	17										223
160	1 210	- 				0		1								210
17.0	213	 			 			1								213
17.5	217				1											217
15.0	220	1:						1								220
18.5	223	- ji			i											223
190	22.	- -														227
19.5	231	1.			i											230
20.0	2.3				1			1								233
7.7.5																237
	4c															1 <u>1</u> 243
	.43															ಚಳುತ

34 47

A schematic calculation of necessary Insulin quantities based on sample input data of food consumption and working power from a fictive diabetic

PAGE C

CALCULATIONS

URI = injection of some units regular Insulin

UDI = injection of some units depot Insulin HL = high limit of BSL (160mg%) LL

in ULL = under low limit LL = low limit of BSL (80mg%)

NEW BSI from					502 (11		. ,			- 10W 1111	0	302 (00	g /0)
from		19.	- 4	- 7	middle]			final	BSL			
PAGE B		SL] "		value	J }	BSL		value	over	low su	gar level?	
	ove		URI	±BSL	BSL	<u> </u>	r HL	UDI	T±BSL	BSUmg%)	4	ULL	
100	1000	1 116	0	1 2000	100	OVE	I IIL	001	TIME	100	nL nL	0.00	hint
103	#	1	0		103		 	1 - ö	 	103	 -	0.00	
107	#	1	0	 	107	-	 	0	 	107	 -	0.00	
170	10		0		170	10		0	 	170	10	0.00	
163	3	1	0	i	163	3	 	1 0	 	163	3	0.00	
157	#	1	0	<u> </u>	157			0	 	157	l	0.00	
150	 		0		150			0	 	150		0.00	
163	3	1	0	!	163	3	 	0		163	3	0.00	
153	 	1	0		153			0	<u> </u>	153	l -	0.00	
143		1	0		143			0	·	143		0.00	+
143	1	-	0		143	l		0	† — —	143		0.00	
143	1		0		143	 		0		143		0.00	
143	ii		0		143			0		143		0.00	
143			28	URI	143			0		143		0.00	
147			0	0	147			0		147		0.00	
270	110	110	0	-112	158			0		158		0.00	
253	93	93	0	-84	169	9		0		169	9	0.00	
227	67	67	0	-56	171	11		0		171	11	0.00	
200	40		0	-28	172	12		0		172	12	0.00	
173	13		0	0	173	13		0		173	13	0.00	1
147		ii	0		147			0		147		0.00	
140			0		140			0		140		0.00	
153			0		153			35	IQU	153		0.00	
167	7		0		167	7		0	0	167	7	0.00	<u> </u>
180	20	20	0		180	20		0	0	180	20	0.00	
183	23	23	33	URI	183	23		0	0	183	23	0.00	
187	27	27	0	С	187	27		0	0	187	27	0.00	
290	130	130	0	-132	158			0	-24	134		0.00	
277	117	117	0	-95	178	18		0	-47	131		0.00	
263	103	103	0	-66	197	37	37	0	-71	127		0.00	
250	90	90	0	-33	217	57	57	0	-94	123		0.00	1
237	77	77	0	0	237	77	77	0	-118	119		0.00	
223	63	63	0		223	63	63	0	-141	82		0.00	
210	50	50	0		210	50	50	0	-138	72		-8.00	SUGAR I
213	53	53	0		213	53	53	Ō	-132	81		0.00	
217	57	57	0		217	57	57	0	-127	90		0.00	
220	60	60	0		220	60	60	0	-121	99		0.00	
223	63	63	0		223	63	63	0	-115	108		0.00	
227	67	67	0		227	67	67	0	-109	117		0.00	
230	7C	70	0		230.	70	70	0	-104	127		0.00	
233 li		73	0 1		233	73	73	0	-98	136	ļ	0.00	
237	77	7.7	0		237 j	77 1	77	0	-92	145	- :	0.00	
240 .	60	<u> </u>	0 1		240	1 08	80	0	-86	154		0.00	
243 +	€3	83	0 1	1	243	83	83	0	-81	163	3 :	0.00	. ,

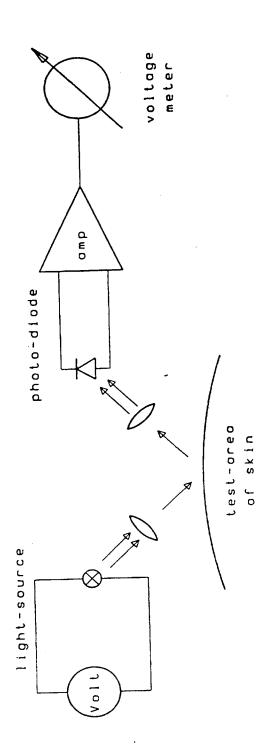
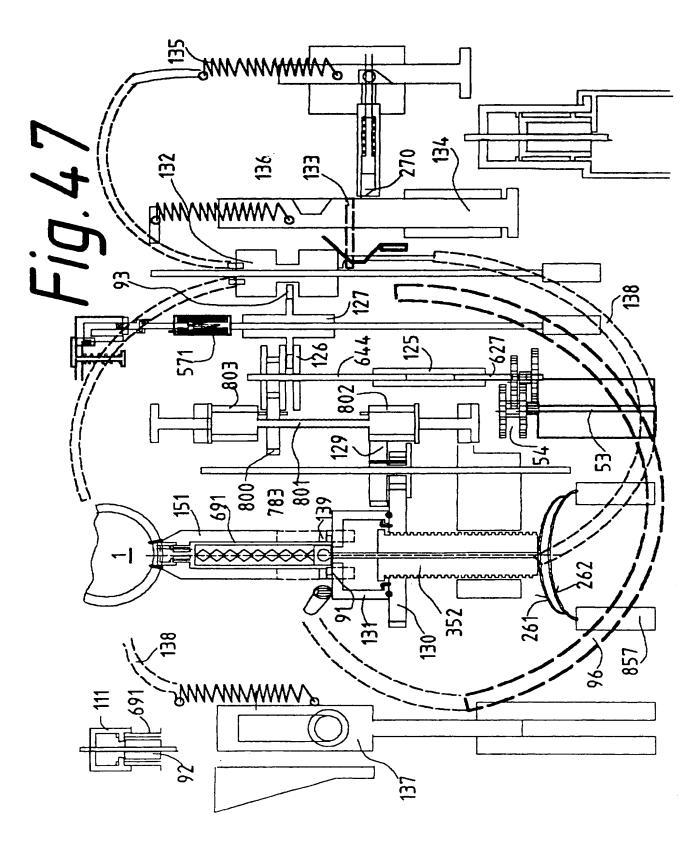
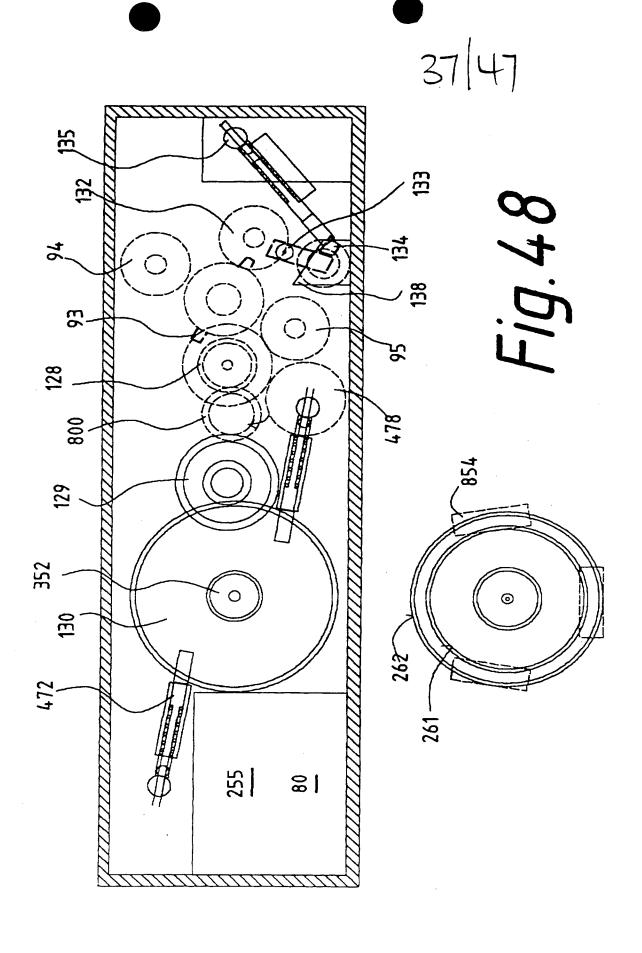


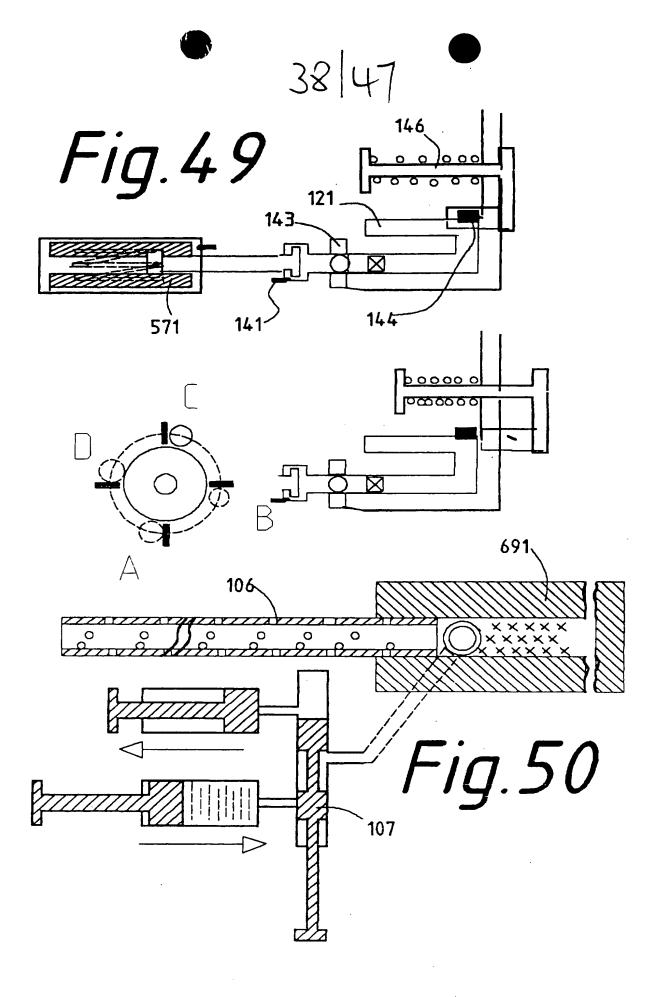
Fig. 46

36/47



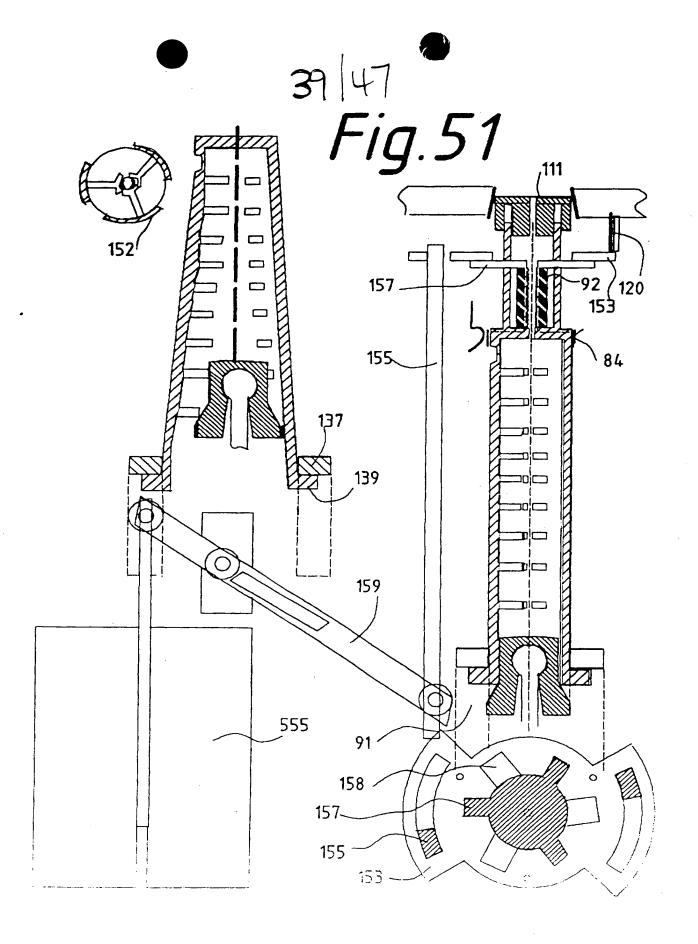
BNSDOCID: <GB___2307960A__L>

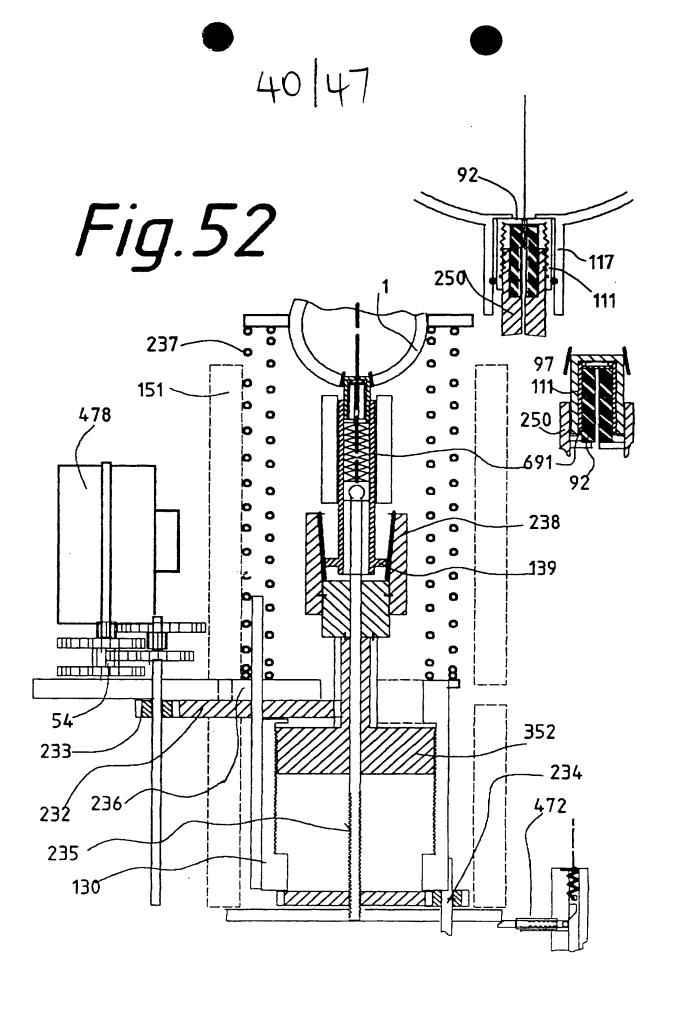


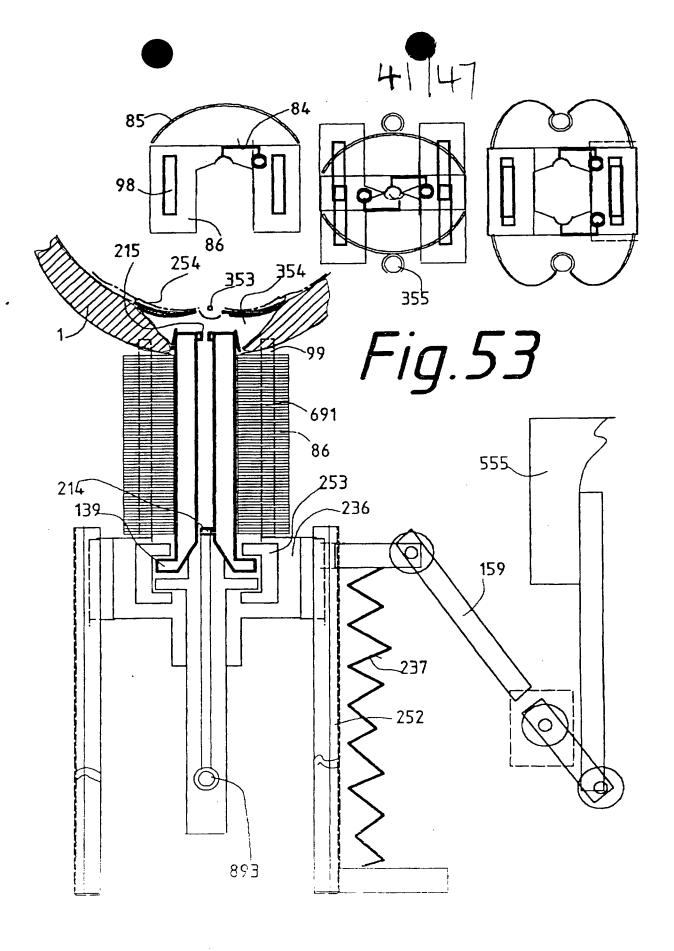


BNSDOCID: <9B__2307860A__L>

A HE ALL LATE OF HEALTH

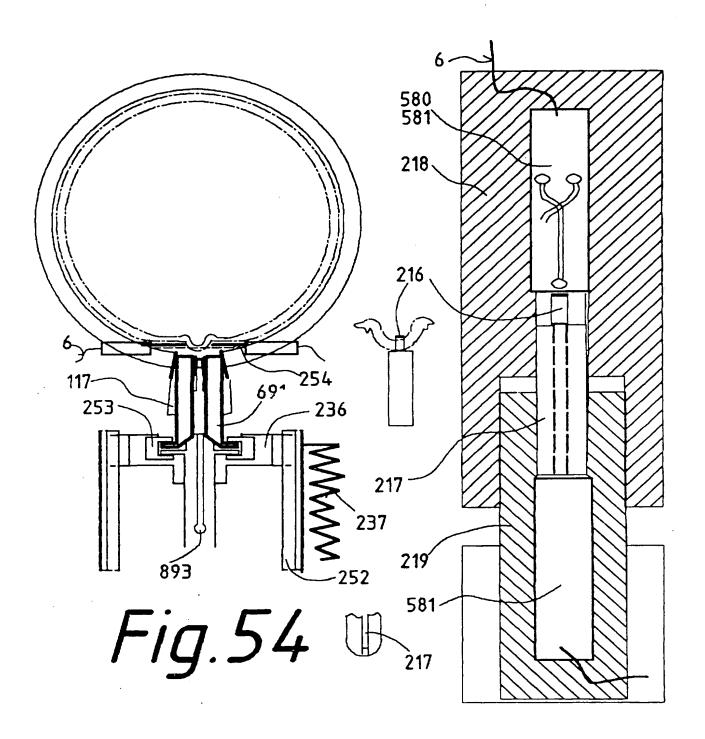


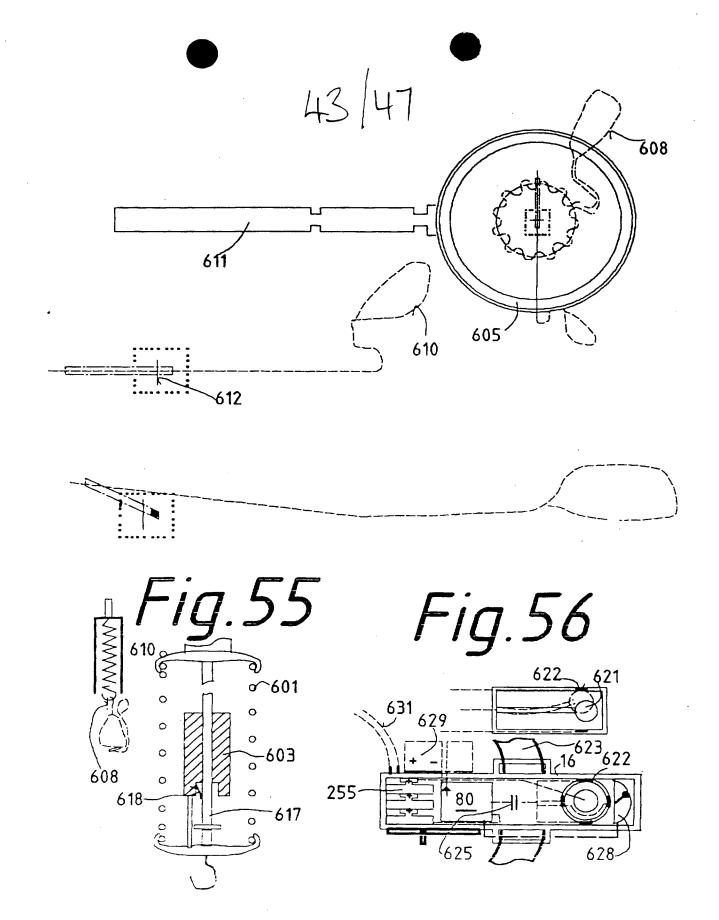


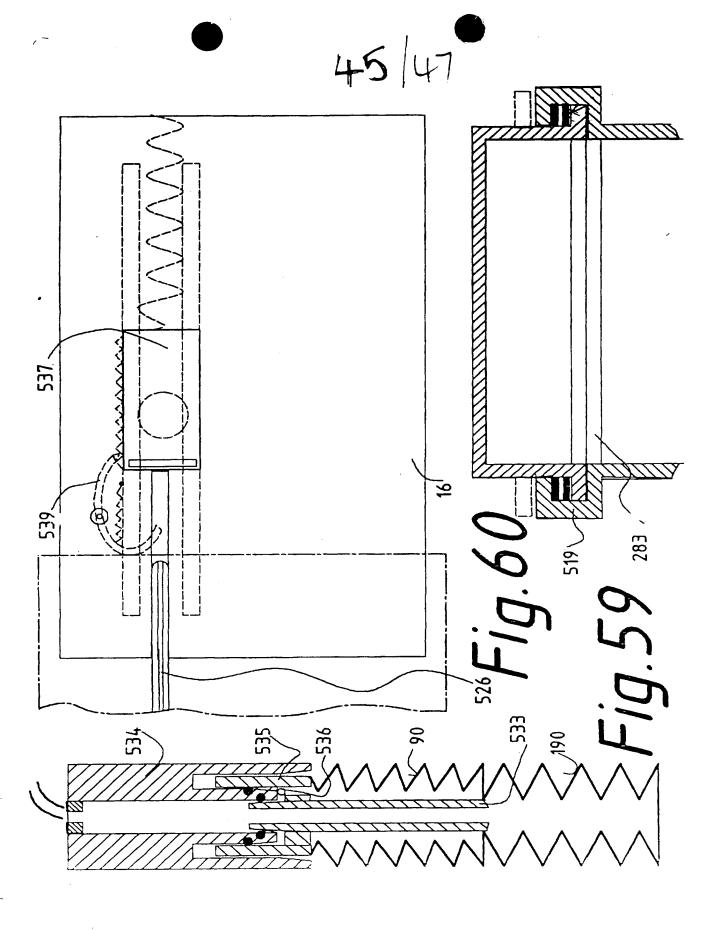


BNSDOCID: <GB__2307860A_L>

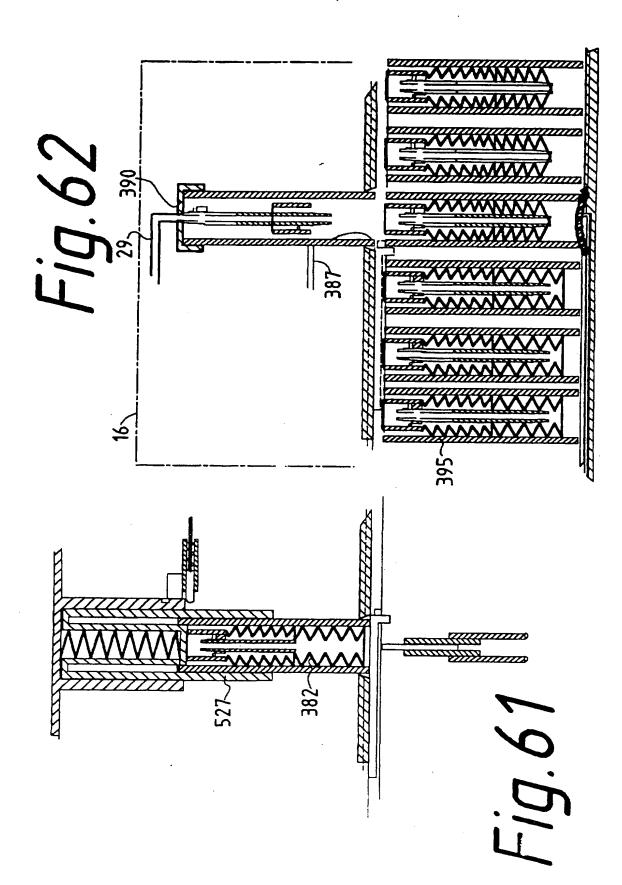
42/47

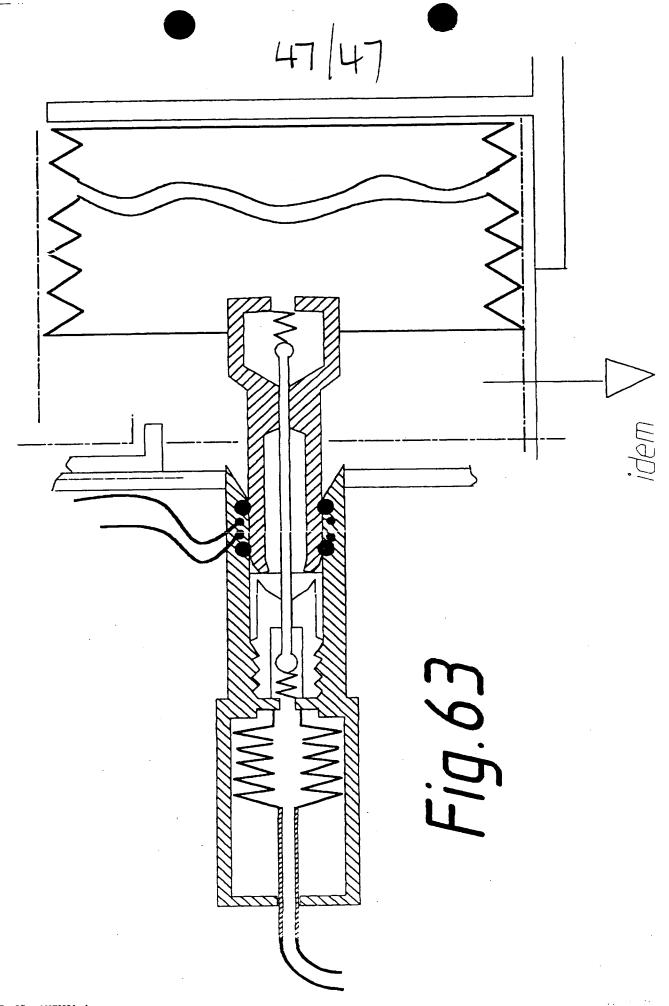






BNSDOCID: <GB___2307860A__L>





BNSDOCID: <9B__2307960A__L>

A Device against certain Metabolic Disorders and a Combinatorial System of its Apply

The invention relates to the medical technique, dealing especially with the treatment of diabetics with insulin. First, the invention is founded on the over pressure or jet injection which came into fashion in 70's and was keept until 1983 for mass inoculation practice.

On the one hand the irritations of the skin through repititive use was caused by tissue lacerations, because the injection nozzle was pressed against the skin in a tissue compressing manner.

In the Patent Application DE: P 37 30 469.0 this need was fulfilled. The present application shall remove a further cause of violent skin irritation: That is, the remains of drug and desinfectant residues in the injection channel of the skin.

Until the glucose measuring by means of laser rays through the skin is practically realized -which could profit by the blood emptiness in the suction cup- the purpose of a measurement through the eye cornea is still enriched by the inventive improvement of performing such measurements by means of a special spectacles, which places the measuring arrangement in the depth of the orbit automatically. Even there gaining of singular measured values during the day is considered as burdensome for the patient as the permanent body contact of a measuring device. Such metabolism measured values there are understood to be offered (generally cable less) to the computer in the injector for evaluation and registration to guarantee the totality of the therapeutic system. The more sluggisch metabolism in the eye chamber gives the inducement to watch for other possibilities of an injury-less metabolism control as supplementation. The habituation on a daily urin sampling can be stimulated by suitable auxiliary means. But also the supplementation of an injection by a separated injection of a kind of sensor bristle, mainly inside of a suction cup, could be useful.

5

10

15

20

25

30

3.5

The production of sensor cannulas, that is to say, of cannulas inside of which a sensor thread is shoved under the skin, is comparatively expensive, mainly exclusively for measuring purpose. Additionally, the sensor thread must be held particularly thin, because the cannula shaft or cover destines the diameter and this even could be lowered to a diameter of 0,32 mm. The main purpose for the treatment remains a painless and minimum invasive introduction of the sensor.

With this application, the functions of a suction injector 10 should be automatized so far as possible. As another unrenuncable scope is set that one to open the lid over the injection nczzle which has an air tightened seat first immediately before the drug administering. Otherwise, drug fluid should be able to be sucked downward through the injection 15 nozzle still before the injection into the suction cup space under the influence of negative air pressure in the suction cup. In such a manner not only the metering could be incorrect, but also air could enter from the suction cup space, inspite of the weak vacuum there, into the injection cylin-20 der space. That could possibly interrupt the inection beam. The necessity of a container as well for the thinning fluid as for water for the cleansing causes an enlargement of the apparatus, for what which encountering was necessary by space saving on other places in all functional 2.5

5

fields.

Prior Art

Proposal was made to measure the glucose content before the eye lens through the cornea by the application of a special contact lens (March, Wayne Front, P 22 38 985; 5 US 3,958,560 May 25,1976). The "device for the destination of the surface centre of an illuminated hole" refers remotly to the proposal for focusing spectacles. (Digital Systems Inc.Arc.Cal. Ind.William Marautelte, DE 25 36 380). Nils Kayser 10 (P 26 06 991, Febr.20,1976) has filed laser measurements including of glucose through a tongue spatula. Arno Mueller attempted it through the lobe of the ear. Wire less transmission of desages and vices found on 😁 Prestek K.and Franzeski M.(DE 30 35 670) as well as by 15 Fishel and Ellentuch (P.32 47 233). Also to be mentioned are the numberous jet stream injectors, as DE P 30 30 671 filed by Hoechst and Mc Kinnon, Charles Neal (Bioject. Inc.Euro Publ.O 427457A2), which is supplemented in this invention with the suction cup and a step syringe, and 20 means for cleansing of the injection channel. In addition to the over pressure or jet stream injection within a suction cup which I filed in DE 37 30 469.0, proposals for a kind of sensor bristle or capillary in a puncture grip are made in Euro Pat.Appl. Nr. 25 O 301165 (published Febr.1,1989). But these sensor elements were introduced into the body by an accompanying lancet or cannula, which should dilate the injury under the skin by swinging movements or rotations for a blood sampling, whereby in a special case, the measuring 30 zone was transferred to the lancet shaft itself (Fig.59, 12). A skin squeezing mechanism is demonstrated in Fig. 61. The efficient introduction of a small sensor between the skin and muzzles, also in a humide area, is intended with the invention now presented at nearly any body 35 part.

Summary Of The Invention

5

10

15

20

30

The proposed task is solved in an example by the emptying of separated piston-cylinder pumps through a common nozzle. Caused by an electrical circuit contact, the pressure donator, here, a solenoid or pressure spring, for the second piston in the cylinder with the skin affinitive or friendly fluid, is triggered shortly before the first cylinder with the drug is emptied, so as the pressure beam is not interrupted. The task of the determination of the triggering of the point of time can also be solved by a computer oriented from the amount of drug which is administered to the first cylinder. According to metering one is fallen back, only for example, to the step syringe (the "pen" system), to avoid detours which are not customary in the trade. During the storage period and during the drug apply into the cylinder, the nczzle is closed by a lid which has a sealing ring toward the area of the nozzle and incandescent wire loop, which is embedded in ceramics, the heating of which by current application causes the evaporation of the water residues on the area of the

one of the two cannulas after the passage of a flap for each of the two mounted toward the metering (or injection) chamber on the end of the cylinder, but which takes place after the rinsing out of said air by means of tissue friendly fluid. Thereby the said lid, of course,

serves for prevention and killing of pathological germ settlement. The cylinders are closed toward the pressure donator by a sealing membrane between the pump rod and the cylinder ledge or rim for the infection prevention.

In the second example, two pistons are arranged one behind the other inside of a commune cylinder. The drug is placed before the first piston, as the rule two sorts

of drugs are used, namely immediately working or regular insulin and depot insulin in different dosages. But skin friendly fluid is also still filled-in before the drug application until the piston ledge openings are disappeared above in the cylinder and therewith sealed. The space between the two pistons is filled up with tissue friendly fluid through the posterior piston. When the pressure denator is activated (it could also be a sclenoid as in the first example), the first piston, subsequent to the drug, is driven toward the nozzle by the main amount of the tissue friendly fluid. As scon as the piston ledge openings are free, tissue friendly fluid penetrates exceptionally from the interpiston space into the interstice before the nozzle, which is left, finally, no more by drug. A chamber-nozzle cleansing is provided at last after each use by means of an injection (or better:ejection) stroke with clean water. The change between tissue friendly fluid and clean water is achieved by valve or three-way-cock. The second example fell back upon the mechanique as it was derivated from a toy auto and described in further details in DE P 39 25 940.4.

20

The demonstration of the power way from the electric motor through different rigid and flexible shafts and toothed wheels on detail was therefore dispensed with, because that would be possible to any skilled expert without difficulty.

Because the scope of the invention, of ccurse, is a pocket portable flat shape, the drug expelling cylinder is horizontally mounted and the nozzle is deflected on the end of the cylinder about 90 degrees from the cylinder axis. It is also possible to stratify drug and tissue friendly fluid inside of a hoselet without separation in a manner as today chemical substances are portioned in the laboratory -even though separated by air bubbles. If that is done quiet immediately before the injection, the mixing through of both fluids will be a desired in-

5

10

1.5

25

30

complete one; also a strong pressure donator (perhaps a piezzoelectric one) can reach the effect of a rinsing out of the skin.

The proposed task of an avoiding of suction influence toward the nczzle is solved by assigning a mechanism for the opening of the lid over the injection nozzle immediately inside the space with negative air pressure in the suction cup.

This lid favorably clings a blind-like kind of leaf spring to the end of the injection cylinder. This can be displaced now as well in a vertical motion as in a radial one out from the area of the injection nozzle by means of a wedge slantily by a lever or directly -as by a bowden wire. But a corresponding drug passage opening in the blind cam provided is brought in a coincident position with the injection nozzle shortly before its function. A nozzle which frontaly leads out from the injector cylinder, if nozzle and blind axis lay excentrically or a sectoral gap, exists in the blind.

 $_{\mbox{20}}$ $\,$ A kind of sector blind can also be turned past the nczzle by

duce special difficulties: namely, to keep the nczzle clean by means of a heating device after the injection; but mainly the necessity of an optical control of the skin with regard to the aptitude for the puncture and this just on an area where the skin clings. The jet beam can thereby also be led obliquely inside of the skin knob, because it however depends on the lengthening of the distance, the injection produces a nearly horizontal projection from the suction cup edge; in such a manner a particularly near and secured skin contact takes place, but slight pressure staggerings can do nothing against this.

an axis in the suction cup roof. The additional tasks pro-

To keep the area of the nozzle clean with heating, a kind of second blind can be fitted over the just decribed one, which contains heating wires. The advantage of such a functional division is that the second blind or cover can

5

10

15

25

30

be thicker shaped and can yet be turned or lifted out of the functional area before the skin is drawn up. The optical survey can still occur in the raising place of the skin. In particular if a higher capacity of the computer of the electric and electronic control unit is installed. In this case the natural skin field structure or patterns can be used as a kind of scale and the reflexion quality (the reproduction of brightness) of the skin area, as it can be ascertained perhaps on a window in the suction cup edge, can be converted to the area which lies before the nozzle. With such a computer analysis, spotted skin colouring (perhaps with freckles) can be considered. The duration and velocity of the skin pattern motion are gloted acurately for such a (arithmetical) conversion.

Even a pigment poor zone of the skin can be steered for the injection over ar electronic control of a ventilation throttle for the suction cup, without the need to break off before the process of sucking of the skin and without need to repeat it.

The minimum demand to an optical skin control is reached with the comparison of the brightness of the injection area and ar adjacent one, still suitably by the proceeding use of device. (Thereby one can be placed on the optical glucometer as customary in the trades). In a special solution, the light ray is projected from the suction cup recent to a kind of mirror nose on the nezzle blind. After the reflexion on the skin, the ray path leads back to the sensor. The mirror nese is moved away from the nezzle before the injection. The measuring can also occur by a light ray which projects from a light conductor end near the nezzle. In this case, the measuring and the elaboration of the result must be effected in the intervall between the blind opening and the injection.

Further features of the invention relate to the sort of pressure donator for the injection rod, the injection cylinder, and injection piston shape for avoidance of pol-

5

10

15

20

25

lution in a permanent operation of the device, and the mechanical gear control as well as the container shape. Besides the treatment of diabetics, the device can be used for the administering of other drugs. It should be menstioned here the periodical heparin injection for the aim of thrombosis prevention. The insulin cartridges were chosen as metering device, as they are broadly customary in the trade with so-called pen-systems, but one could use also any other metering systems. Stack containers in row, that are folded 10 bellows, are described as alternative for the employment of step syringes. The cannula, which serves for the communication to the next container, can be removed. A folded metering chamber on the foremost container, which is connected with the drug inlet opening into the injection cylinder, de-15 livers the drug in the total of single dosages. For that, the metering chamber is impulse-like, compressed by an eccentric gear or solenoid.

A water container was to schedule, because the metering piston and (metering) cylinder as well as the nozzle had to 20 be cleaned after each injection from the salt of the thinning fluid (shortly: thinner). Thinner and water are suitably stored in high elastic containers and combined in an exchange-container unit. Because also in this case no amount of air should enter into the closed fluid system during the 25 container exchange, these elastic containers must be beared in a further rigid container and must be exchanged in the said one. The inner container are suitably set under gas pressure in a further container of the device. This is only allowed for the short period of the filling up of the in-30 jection cylinder or of the cylinders; in any case, such a timely limitation seems to be suitable for the purpose of keeping the valve equipment simply.

Preferred fittings of the thinner and water containers consist of two folded bellows, which are separated one from other inside of a plastic or pasteboard cylinder by the portion wall of the latter. Therefore, a kind projecting collar 5 edge in the middle of the pasteboard cylinder is pressed against a container seal. The two afflux connnecting pieces for gas are firmly installed in the device container wall. The derivation of thinner respective water takes place from the folded bellows through cannulas which are connected with 10 hoses. The former pierce the stopper membranes in the centre of the cover cap, which can be screwed on, and from the centre of the bottom of the uptaking device container. The security of the injection cylinder or the cylinders on the introduction side of the piston against pollution is effected 15 by a roofing over with a membrane or a folded bellows. The filling up of water or other fluid in the interstite between protective membrane or folded bellows and the rear piston face is a new procedure to prevent the injection space against an entrance of air. For an enabling to diminish 20 the amounts of auxiliary fluid (thinner) and water, if smallest drug dosages are used, a amount or dosage limitation is introduced also for these. The limitation is approximately conversly proportional to the drug dosage. (A too frequent necessity for a container exchange or too big a volume load 25 of the device would otherwise be the consequence). The dosage limitation is preferably brought about here over a screw, which activates after the back movement (or lifting) of the metering pistons, and this is done through the roof of the protective folded bellows and thightened to that. 30 When the control gear, in the here preferred linear arrangment, returns after the injection, the desage limitating screws are sunk again into their injection cylinders. (The gear should not work to the screw the insulin cartridges, as long as they are not yet emptied or should be ex-35 changed).

In nearly each case, thinner is mixed to the cylinder space, destined for the drug, so as the smallest dosages still can be turned into an injection beam.

A pressure gas source can be used as pressure donator in one example for each injection cylinder of the device. Two strong pressure springs, one for each injection cylinder of the device (namely one spring for the drug thinner mixture and the other for thinner which washes the skin out), serve for a pocket portable device dealed with here. The pressure springs are lifted to produce a strong but slow motion moment through one or two wedge slides into their stop catch. The latter is bolted by a release fork. The release fork again is shot up by means of an auxiliary spring.

In an examplary sclution the shortening (or lengthening) of the switching distance in a Bowden cable opens the blind before the nezzle still before both metering pistons with connecting straps between pressure spring and injection cylinder are released. The injection distance for both cylinder can be adjusted by a slide (bar) which partially covers a release slot on the release fork, whereby this operation 2 C is coupled with the metering and adapted to the filling amount in the injection cylinder. Another solution uses three solenoids for direct stroke for the triggering of the three functions. But all three and further functions can also be operated by one sclenoid only by means of a rotation 25 mechanism for a drum with conducting grooves (a thrust-torsion-mechanism) which causes a partial rotation with each stroke. The switching periods can still be essentially shortened by tensioning a tension spring during the stroke in a certain angled position of the hammer (connected with the rod of the solenoid). A rotating disk with sectorally radial passage can free the hook on the cross bar of the tension spling at any desired functional phase for

- 10 -

switching purposes.

The activation delay of the sclenoid can be under bitten in such a way. (Frequently smelts with rotation mechanism in ball

pens for the blocking of the writing lead to a similar explanation).

A gas jet pump is used for the negative pressure production in the suction cup. For the handy device, manual pressure is exerted against four pressure springs, guided in four tube sockets at the housing corners toward a bag which lies

- 10 behind a separated cover sheet. The produced over-pressure is transmitted through a valve to the container for the folded bellows with thinner and water during the drug metering. Because the bag is broadly connected as well with the lid as with the cover sheet of the housing of the device,
- of the four pressure springs, the suction being effective through the before mentioned valve in the suction cup.

 The functional security postulates a short switching period between the raising of the skin in the suction cup and the
- 20 injection release. When this was not produced by a special sclenoid, this task was solved by attaching the release of suction and injection to the same operation wheel. The latter still works against a spring during the suction release in two examples. This period remains up to the over-
- coming the pressure point, that is sudden change of the maximum spring tension for the decision for the injection on
 the electronic control unit or part -according to the information over the skin contact by contact-switches immediately
 near the nozzle, and according to a foavourable result of
- 30 the optical skin control. The spring accelerates then the phase of the injection release. But the release operation can still be interrupted before the turning over of the pressure over the pressure or summit point.

- 11 -

A centrifugal switch for the switching over comes into question for two separated functional blocks - for a series of special operations- anyone of the considerable number of variations for the control gears.

- 5 A roll which has a switching pin (or slide) in a radial bore is driven by an electrical motor. It depends on its velocity during the first rotations if the pin or sleeve is fixed on the inner axis-up to the end of a spiral inner groove-by a spring or by permanent magnets.
- 10 with a high velocity, the switch pin or sleeve enters, outside the roller, the worm formed groove guidance of the outer cylinder which surrounds the roller. The motor power is transferred then (in the related working direction) either to the inner axis or to the outer cylinder, the rotation of

15 which is mediated to separated functional blocks.

As an alternative, a three gear unit is demonstrated. Terminal thrust metions, produced by a screw, are thereby transferred to a control pinion of each functional block by means of a bar. The driving wheel or centrol pinion is

20 shifted along the square motor axis -tracing the transmission toothed wheels for the reduction of the number of revolutions- one after another into the mesh with three operation wheels for the functional blocks.

This shifting increment is rendered possibly over an over-

- 25 bridging sleeve of the control pinion axle as a prolongation of the mctor axis. It is limited in each case by a cross cam peg inside of a switching sleeve stationary to the shifting direction, the cam peg being guided in a slanting inner groove of the sleeve. The groove has notches which corres-
- 30 pend to its meshing position between control pinion and operation wheel, which hinder the cam motion. The latter falls in a counter notch which hinders the return into its exit position with a slight rotation by the slanting of this counter notch under the influence of a pressure spring 35 which counteracts to the cam movement.

The cam is shoved into the next higher stop notch with an renewed sliding movement of the bar by the carriage of the last connected functional block in the final working phase. After two such shiftings, the cam falls back over a steep flange of the groove with following longitudinal groove in the switching sleeve into the exit position. The shifting moment of the bar is maintained to reach the proper effectiveness of the carriage movement of the next functional block by an additional toothed wheel which is shoved up to the bar and control pinion on the control pinion axle, separated from the control pinion by a pressure spring. This toothed wheel has maps toward the control pinion which mesh with naps of the while one touches the other, and the toothed wheel rotates freely around the axle. The additional toothed wheel is then taken, by the pinion. If the pressure from the bar releases, the additional toothed wheel, which transitory enlarges the pinion functionally, leaves its map meshing with the pinion by working of the leaf (or pressure) spring between the additional toothed wheel and the pinion until a new bar shifting by the carriage of the next functional block in its final phase is produced. The transport of the bar by the carriage -finally also the motor driven screw- takes place, for example, by leaf spring with wave profile, on which the cross stay of the carriage 25 temporarly rests during its passing over. Another solution allows a springing pin to mesh on a carriage between the teeth of a toothed wheel (if only moving in one direction of a ratched wheel) and effects a partial rotation of the latter during its passing over. 30 Both devices can also serve for the release of lid stops, tension stops for a squeezing device etc., over levers and tow lines. Especially, release operations can be also produced electrically by one or more solenoids in their respective traction functions. 35 The function control of the mechanical gear unit results

electrically over contacts

5

10

15

mainly or the toothed wheels for the electronic control unit. Thereby, additional contact tracts arranged along to a sliding screw way can induce the motor to running in staccato, to combine an altogether quick thrust motion with precision of the choice for the final point, perhaps in metering. This acceleration of the running up is of importance mainly then, if the filling of the injection cylinder with the drug occurs first during the skin contact. This can be suitably done for an alteration of the dcsage in the last second, 10 but on the other hand a trace of thinning fluid can be delivered out of the nozzle toward the passing past skin with the aim to reach an airless metering of the insulin which is now admixtured. In other words, the dislocation of the injection or ejection nozzle into the area of the suction cup edge is very advantageous. The injection distance without tissue contact is particularly long but without the choice of an oval outline for the suction cup along the injection direction. Such an errangement even can save an opening mechanism for the lid blend which covers the nozzle or it can simpli-20 fy this. (The blind consists, in an inventive example, of

which the optical control device also terminates).

When the nozzle lies already in the level of the damming

up or upsetting area of the skin, then it is already closed up by the skin before the negative pressure works in the suction cup; during the suction, the skin passes the nozzle permanently sealing the same. This process can be observed by means of a special window by light measurement. Light can

a ring which is shoved upward by the skin itself and on

be projected thereby from an angular or bent las or transparent plastic surface to the skin, but especially it can be reflected in a radial projection to the nozzle and from there transmitted to the sensor for measurement or ascertainment.

- 1 if -

The electronic control unit, respectively the computer is abled to attach the observed skin parties with the nozzle in respect to its position according to the skin patterns and to put it in relation to adjacent or ealier stored measuring results of the skin surface by comparing the brightness. But the position of the skin before the nozzle can be shoved by influencing a nozzle or valve between the suction cup and the outer air in such a manner as to avoid an injection into skin areas with suspected reflexion valu-10 es. If a "leak" of the suction cup space is planned-in from the beginning -but before the reventilation- the selection of the injected skin area is effected by the choice of the moment of injection. The same arrangement (eventually also additionally) can be made for the skin selection for measur-15 ing use, because measured values can be transmitted to the injector not only through cables, electromagnetic or acoustic waves from outside -perhaps as glucose measurements by laser through the skin from outside-, but such measurements can also take place inside the suction cup. 20 The registration of functional dates is nearly sufficient and ensues again suitably in connection with the charging device for the battery from the mains. With regard to the programming of the device one comes back to the sclution ways as they are given in PCT/DE85/00113. 25 The rings, which serve for program adjusting and which were rowed one above other are now replaced by knobs which are rowed side by sede along one device edge (better: wall). A locking up knob is here also scheduled to release

30 An improvment in the direction of an increase of liberty for the live style consists of rendering possibly to suitable users, to adapt also the dosages of depot insulin to the respective course of day, that means a daily new programming. A screen raster of sensor contacts on a housing

the allowed decisions of the user in steps.

35 broadside is therefore provided, supplemented by an -eventually interrupted- fluid display ledge, which demarcates about a half or full day interval starting from the actual clock time. The patient is now able to indicate his intended food uptake also with regard to the glucose contents respectively in triangle shape by means of spreading the sensor contacts classed with the intended time interval.

- 5 Illuminated diodes are suitably classed therefore to make the choice visible. The glucose contents corresponds then to the breadth of the above standing triangle base, to the distance of the triangle point below the velocity of the glucose resorption. The extent of bodily activity is ex-
- 10 pressed in lateral rectangles time coordinated in watt.

 Exceeding from actually measured glucose tissue levels and with consideration of the input of individual working constants of insulin, the height and the mixture relation of the insulins are now made coincidently and are administered
- 15 by the computer, unless it is not necessary to warn against absurdities.

During the contact of the device with the charging device from the mains, the installed printer reproduces measured values, patient inputs and delivered dosages in numbers

20 and graphics, and it permits the control.

The optical skin control can be ensued also through a mirror over the nozzle on a blind which is then drawn off. A heating spiral is also suitable for the environment of the nozzle, the former being eventually connected with the blind and

25 capable of being shoved away before the injection.

An optical skin control is also important at the device before puncture. It can be directed, for example, from the suction cup roof through a mirror toward the injection area, but can also be effected through light conducting fi-

30 bers, nearly parallel, near the cannula shaft (her: nczzle).

Mainly advantageously the optical skin control is undertaken by a kind of blind visor with a central hole near a suction cup edge, so that the suction has still enough

35 elasticity to enter into this hole and to build a little buble against the puncture area, where a light beam runs tangentially through the smal skin bubble to the sensor.

The customary urine sugar control causes an inconvenience mainly in the form of the day profile (or sampling), because a large collecting container must be carried along everywhere. For that we recommend to urinate into a little folded sack directly over the toilet. The sack is then cor corded up above and hung on a spring-balance, which can be integrated in the device, transferring the respectively ascertained weights, as approximate urine volume data directly to the computer and data store. A customary test strip is inserted then into the sack bottom(manufactured), so that its free end can be grasped from outside. The sack is opened below by tension on a prolongated belt or this free end of the test strip after a clock alarm; the sack is thereby emptied into the toilet. The test strip can be tied off from the sack through a draining sheath, and an optical 15 brightness control in the device can be directly transmitted to the computer.

Eventual sugar contents of the single urine sample are calculated, but also the averidge sugar contents of all samples after the last meal, input by the patient, and the sugar concentration of the urine from 12 resp.24 hours. Ar additional test strip parameter, perhaps for urea, can be employed for the control of the correctness of the sampling.

But a sensor bristle, resp.a sensor thread, can be shot through the skin from the suction cup edge for a tiscue sugar measurement, which consists of material which can be reabsorbed. The bristle or thread can then be shoved further along into the subcutaneous tissue. (The entrance of the sensor bristle is rendered possible by a high initial speed similar to fluid just also for a flexible material). At first, the thread must be embedded into a kind of chuck similar to a drill, with the aim to be able to pusch it with the chuck in the longitudinal direction without a

lateral evasion of the thread. But the sensor thread can be likewise produced as a drill with helical threads on its front end and can be led under the skin through a skin pore with rotation by means of such a drill chuck, perhaps by a weak rubber tube (end) with big walls, which is compressed. For a further thrust, either the thread reserve is heared inside of a folded bellows on a kind of cross disks or or supporting struts which project from wall segments of a longitudinal slotted plastic sleeve nearly touching one another. The latter are driven asunder with the wall segments of the sleeve one after other by cone. The point of the cone is connected with the end of the sensor thread, while the cone base has a bowl or map for uptaking the guiding pin for the thread thrust. Because a cannula wall is saved, if a sensor bristle is used, the latter can be produced somewhat thicker by meeting with the endowing of chemicals for influencing of the current and with the apply of a outern protective sheat against a diffusion of the chemicals into the body. (The skin which is thinned by the stretching during of its raising, eventually supported by adhesive or squeezing means, reduces moreover the extent of the scar by the injury). The arrangement for the introduction of a sensor bristle can be suitably coupled with the equipment with a nozzle for the pressure or jet injection in one suction Material which can be reabsorbed are preferred, therefore, because the breaking up of a sensor thread can nevermore be excluded before by technical distubances before the retreat of the thread. The use of polymerizated terephthale acid and polylactacid is proposed to which the measuring active substances (as NAD-GCD-Perid for the active and sepharose-convaline-A for the passive electrical sensor) can be bound. Mainly, the polylactacid has distinct hygroscopic properties, which is important for the uptake of tissue fluid. The threads or filamenta of the molecule can be turned as a drill before they are ccated with a protective film (perhaps with polycarbona-

5

10

15

20

25

30

te). In this way a kind of drill could be produced. An introduction of measuring substances into the body could be avoided, if a measuring thread which is not endowed with such substances could be shoved under the skin (a thread perhaps of silk, which is hardened for short time by formaldehyde of 2 to 5 per cent). The thread can be retrieved, if it is saturated with (body) fluid, into the hose end, and the contained glukose can be brought in reaction with the measuring layer, which is

10 inlet in the bore of the hose end.

Threads which are endowed with a measuring layer contact a metallic coat inside of the hose end after being retrivied therein. The current conduction to the measuring instrument is performed by the respective wires. If there

are two conductive zones longitudinally separated, the hose end must be secured against rotation because of the closing of electrical contacts (perhaps by derivations of the diameter from the circular shape).

The device for the introduction of a sensor bristle can be

operated also with a gas pressure capsule. For the driving of the sensor thread or bristle under the skin by the gas pressure beam, the bristle end must be enlarged and stopped at a narrowness on the end of the supporting sleeve. The current measurements can also be done outside of

the (supporting) sleeve between piled up stacking sheets after the sensor thread is drawn back from the skin. (This can be done but also here inside of the sleeve if the respective metallic coating interior is present with contact derivation outwards).

30 If a metabolism measurement (of any interesting substance, as glucose, but also cholesterol and others) is chosen by the reflex optical way with use of colour changing agents, two very small cylinders can be punched out of two different reaction surface sorts customary to test strips. Two of these respective cylinders are then

stuck together in such a way, that both colour reactive -19 —

layers bound the total cylinder each on one side. The total cylinder consists mainly of hygroscopic material (as kieselguhr or silicagel). Such a reaction cylinder can be firmly stayed onto a carrier thread or pin and still even pricked into the skin, whereby the thick carrier works like the disk of a drawing-pin. The metabolism measurement is performed after the input of the carrier thread by laser scanning on both ends; on the carrier side suitably through a (central) bore or channel of that. 10 The arrangement for the introduction of a sensor bristle can be suitably coupled with the equipment for the pressure injection in one suction cup, those fittings facing then one with other. When the period for the saturization with tissue liquid can be held shortly enough, an additio-15 nal scueezing device, perhaps by means of two slides resilient one against other, can be saved. The pressure injection otherwise ensues with a new sucking on after the metabolism measurement is completed. But the diagnosis with the sensor thread can also be transferred into a separat-20 ed device housing. If pulver injection of solid drugs (perhaps in crystalized condition) is applied, pressure gas replaces the "washing out" fluid for the injection channel.

A measuring cannula can also be introduced urder the skin into the liquid sea over the muscle skins or fascia. The cannula consists of a capillary which is drilled in or shot in. Such a capillary can be also endowed outside or inside with a measuring layer for metabolism measurements and it can also serve for the injection of fluids (after the measurement). But the capillary wall can be punched and serve the drainage of tissue liquid toward a measuring zone in the sleeve for the capillary; additionally, of course, to the injection of the drug or medication.

25

The mentioned chuck for the motion of the thin sensor bristleor thread consists perhaps of a thick walled soft rubber tube or hose end which is compressed by pressure in a longitudinal direction. For the further advance, the thread reserve is stored either inside of a folded bellows on a kind of cross disks between the fold depressions or on supporting stays, which nearly meet in the center and project from the wall segments of a longitudinally slotted plastic sleeve. The supporting stays are driven asunder, one af-10 ter the other, with the wall segments of the sleeve by a cone.

The point of the cone is connected with the end of the

sensor thread, whilst the cone base has a bowl or nap for the uptake of the guiding pin for the thrust in advance: 15 Because the wall of the cannula is omitted, if a sensor bristle is used, the latter can be produced slightly thicker, what is opportunely for the endowing with chemicals for the influencing of current and to the coating with an outer protective layer against the diffussion of 20 chemicals into the body. (The skin, thinned during its raising eventually also with adhesive or squeezing means, anyhow makes the remaining scores smaller). Material, which can be reabsorbed, deserves the preference, because a breaking off (of the sensor thread) can never-

25 more be totally excluded.

The device for the introduction of the sensor bristle can be also operated with a pressurized gas capsule. If the gas pressure beam drives the sensor thread or bristle under the skin, the end of the bristle must be enlarged and arrested at a narrowness or the end of the bearing sleeve. The current measurements can be performed between piled up stacking sheets outside of the supporting (or bearing) sleeve, after the sensor thread is pulled out of the skin. (But this can be done also inside the sleeves, if these are appropriately coated with metal interior with contact derivation outwards).

30

35

The threads which are endowed with the measuring layer contact, after they are drawn back into the hose end, therein with a metallic layer over which the current conduction is performed through the appropriate wires or leads to the measuring instrument. There are preferrably 5 two conducting are separated longitudinally by an insulating zone, resp.twc insulating zones. If the period of saturisation with tissue fluid in the sensor thread can be held shortly, an additional squeezing device (perhaps by means of two slides or plates 10 under the suction cup edge springy one against the other) can be saved, when a suction cup is used. In other cases, the pressure or jet injection through a nozzle occurs after the metabolism measurement, interrupted by a renewed sucking-on of the skin. 15 But the diagnosis with a sensor bristle can also be transferred in a separate device housing. If pulver of a solid drug is injected (perhaps in a crystalline shape), pressurized gas replaces the "washing-out" or thinning fluid for the point of entry into the injection channel. 20 But a measuring "cannula" can also be introduced under the skin into the liquid lake over the muscle skins or fascia which consists of a drilled or shot-in capillary. Such a capillary can be, inside or outside, endowed with a measuring layer for metabolism measurements and it can 25 also serve for the injection of fluid (after the measurement). But the capillary wall can also be punched through (with finest holes) and can serve to the drainage of tissue fluid into a measuring zone in the sleeve or capillary; additionally, of course, the capil-30 lary of such a type can also serve for the drug injection. If a double-sided colour measured cylinder is used, the measuring is achieved by laser scanning in both ends of the cylinder; on the side of the carrier suitably 35 through a bor of it. Instead of a laser beam, a light beam can be used for the optical reflex measurement with - 2**2** -

BNSDOCID: <GB__2307960A___>

ancillary lens (also by use of light conducting fibres, preferably with the method of optical soupling with crossing and punctually welded fibres).

Mainly advantageous is the fixation of a minute colour-changing sensor cylinder on its tube-like carrier by shoving its one end into the end of the carrier tube with a sealed connection (sticking or welding) of both portions. A Pen-like instrument with such a "drawing-

a round end around the nozzle for the shot-in of the sensor cylinder. Such a instrument can be pressed against any skin parties with elastic subcutaneous conditions.

pin sensor" needs not an optical skin control and has

5

Short description of the drawings

Fig.1 is a schematical reprentation of a jet injector with suction cup in longitudinal section in a scale of about 2:1 with procfive lid for the suction cup inclusive the nczzle.and with a double injection cylinder and two solencids as pressure donators.

Fig.2 shows in longitudinal section in a scale about 3: 1 a jet injector with suction cup with one double piston

oylinder and water cleansing device, driven by spring power, but indirectly by an electrical motor. Below a valve disk for fluid in cross section.

Fig. 3 shows in a plan view in a scale 2 : 1 a valve (circle) with an slant lever. The latter is shifted between

two lock pins with a frame with slot along a bar.

Fig.4 shows in longitudinal section in natural size a

motor driven control gear for several operation. Above, to
the left a cross section of three gear wheels with shiftable special housing.

20 Fig.5 shows in a longitudinal section in a scale 2: 1 a special type of a double piston cylinder with an inner valve.

Fig.6 gives a jet injector with suction cup in a longitudinal section in naturale size. Over the tublet(8) is

25 drug filled into the anterior portion of a hose erd. The latter is emptied by a sclenoid stroke or a terminal folded bellows.

Fig. 7 shows an injection cylinder with rectangularly deflected nczzle in relation to a suction cup, to the left in a longitudinal, to right in cross section, both in

a ratural size.

Fig.8 gives a block diagram over an entire device as therapeutic system with optical skin conrol in a suction cup and wire-less connections between the electronic con-

trol unit of the device and separated transmitter-emitter portions, one of these on a kind of watch-bracelet.

- Fig. 9 gives in longitudinal section an overview over the main device connection of the single portions of the device, whereby the largest length is shortened about to 70 percent and the suction cup is respectively diminished.
- Above in a detail with a special arrangement of the supporting columns for the strong pressure springs as pressure donator. Above, to the left, the lock pin for the auxiliarry slide for the release of the two pressure donators in cross section.
- 10 Fig.10 shows the detail of a control gear for a jet injector in longitudinal section in a natural size. To the right, the roling up of the inner groove of the tube socket (786, in the longitudinal section) is shown in a scale of 2 : 1.
- 15 Fig.11 shows the variant of a centrifugaly operated switch in longitudinal section in a scale of 2 : 1.

 Fig.12 gives the example of a lever thrust transfer to two release functions with a trigger slag mechanism in a cross section and a scale of 3 : 1.
- Fig.13 shows details of a power transfer from a motor(not shown) to operating functions(not shown) in a natural size and a longitudinal section. Below, in a cross section and a scale of 3: 1 a ratched toothed wheel with a partial breaking off to the left.
- 25 Fig.14 shows in a natural size, above and in the middle in a side view power translating toothed wheel of the device according to Fig.9. Above the large toothed wheel for the sliding screw, which tighten the strong pressure springs as pressure denators for the fluid ejection. Under that,
- in the middle a projection of power transfer to the operation wheels (for example for metering) in different section levels. To the right, a longitudinal section through the detail of any toothed wheel (from the side view) are shown, quite below an sideward (vertical) overview
- 35 to demonstrate the overlapping of the toothed wheels. Fig.15 shows in longitudinal section on a scale of 2 : 1 the exchangeable fluid container unit for water and thin-

ning fluid. Below, to the left and to the right, preferred variations of the terminal portions of the container assembly from above is illustrated. Fig.16 gives below, to the left, a partial longitudinal section through the pressure donator of the Fig.9, illustrating the power transfer from the outern strong pressure springs to each of the two injection cylinders. Above, to the right, a cross sectional view is given to demonstrate the joining together of the injection cylinders into the common nozzle and the valve flaps behind the fluid 10 supply tubes (not shown) into these cylinders. Below a single piston injection cylinder is shown (in the middle) in the cross section with the mechanism for the metered influx of thinning fluid and the folded bellows with a insulating fluid for the protection against pollu-15 tion. Above the detail of two beveled wheels as alternative rotation transfer. Below, to the right a longitudinal section through the two injection cylinders in the level of the valve flaps with the influx tubes for two drugs and 20 the thinning fluid (dashed drawn). Fig.17 shows to the left in vertical or cross section a detail of a pressure spring block or basket with a space compensation through a slot outside over the housing well during the release of the pressure donator. 25 Above, to the right, in a horizontal or longitudinal section the function of both release slides(268) for the pressure donators are illustrated (c.p.Fig.9). In the middle, above the possibility of a locking device for a inner and outer pressure spring is explained during the spring release. Under that, the stage of pressure com-30 pression is shown, all that in vertical or cross section. To the left of the just described blocks or baskets, a side view is given toward one of the release slive with the mechanism for an adjusting of the release interval between the two pressure donators. (Under the upper 35 release slide vertical section through the latter along dif-

ferent section lines).

- B) Below, to the left, a schmatic vertical or cross section the variation of a pressure donator with lever transfer of spring tensioning by a wedge slide is shown.
- C) Below, to the right a further variation of the pressure denator basket is schematically shown with a shorten-

ing of the heighth by a clamp-like frame, to the right partially in different functional stages.

Fig.18 shows above, to the right, a further detail of the pressure donator basket (c.p.Fig.9) in a compressed (above)

and relaxed (below) condition with the wedge slide for for the pressure tightening and a partial view of the bag(257,c.p.Fig.21) for the suction production.

Above, to the left, a slant lattice net is illustrated for the support of the pressure springs (or donators) in a ver-

15 plan view.

In the middle, a horizontal or longitudinal section is given through the lowest portion of the strong pressure springs and a plan view toward the wedge slides and the roller bearings for the lattice net on the former.

20 Below, to the left, the transversal section through the functional divided wedge slides along the section line. A - B of the horizontal section.

Below, in the middle, again a the mechanism for a delaying of the release of the inner strong pressure spring is shown

25 on a vertical or cross section.

Below, to the right, a sketch is given of as pressure donator release by an articulated support, which can be tilded.

Fig.19 describes, above in a vertical section, in the mid-30 dle and below in vertical sections the configuration of a valve control for fluid and air, if a bag (Fig.21) is used for the production of as suction for the skin fold and an overpressure for the flashing out of fluids.

Fig. 20 demonstrates in a kind of block diagram the

35 distribution of suction and overpressure from the bag and the change between the transport of thinning fluid or water into the injection cylinders.

- 27 -

Fig.21 shows a vertical section throug a device according to Fig.9 with the illustration of the bipartite bag for the manual producktion of suction and overpressure between a firm cover sheet of the device and a lid which is movable against four pressure springs (from wich two are shown by 5 the section line near the side wall of the housing. The locking and release device for the mentioned pressure springs is still demonstrated (Above to the right a transversal section through the detail of the locking carriage over that). Above the detail of a connection 10 between the bag and the lid rep. cover sheet of the device. Fig. 22 shows schematically three sclenoids working against three release function: above for the auxiliary slide for the pressure donator release; in the middle, for the expansion of the suction producing bag; below, for the re-15 lease of the drug and fluid ejection stroke. To the left the detail of the end of an injection cylinder with sectorally slotted blind for the opening of the nozzle be the wedge slant of the release slide. Fig.23 gives a horinzontal section through a double working 20 scilenoid with a thrust-rotation device for the the operation of any functions one after the other. Below a transversal section along the section line A - B of the horizontal section. Fig. 24 shows an enlarged the electrical current transfer over a enlarged toothed wheel with sliding 25 contacts for the message to the electronic control unit. To the left a transversal section is given, to the right a horizontal section. Fig. 25 shows, above in a vertical section, a suction cup with a dcuble blind for the injection nczzle and a 30 optical skin control device. Below a horizontal section through the details of the two blinds is given(enlarged). Fig. 26 shows an enlarged vertical section through a suction cup (and a side view toward an injection cylinder) with another nozzle blind and an alternative for the opti-35 cal skin control. Below, to the left a partial horizontal section is given, to the right a further enlarged detail

-28

BNSDOCID: <GB___2307860A__L>

of the blind area.

Fig. 27 shows an enlarged vertical section through a suction cup with an annular blind which raises, when the skin is sucked up. The optical skin control device is mounted on

5 the blind, which is shown to the left in an elevated, to the right (half) in the lowerd stage. Below a plan view to the blind.

Fig. 28 shows vertical section near an injection cylinder, which is laterally installed, through a suction cup.

10 The optical skin control by a photo emitter and sensor occurs here on a window, which is as an enlarged detail represented below.

Fig. 29 is a plan view to a control pannel of a device according to Fig. 9 and another devices. The adjusting

- 15 wheel are sectioned, through the breaking of near the suction cup two injection cylinders. (The sleeves with sensor threads an small folded bellows on a chain belongs to a device as in the Fig. 47-54). To the right a the virtual image of a computer calculation with the programme
- 20 inputs for planned meals and work capacity in relation to a metabolic effect by insulin.

Fig. 30 shows the enlarged detail for the program key and its aresting ledges according to a control panel as decribed in Fig. 29, above in a vertical section, under that

25 in a horizontal section. Below a side view in the direction of the aurow.

Fig.31 gives a schematical side view of a device composition on a reduced scale. To the left the housing of a jet injector in ware-less conection with a housing with the

30 *is shown electronic control unit and the stacked on additoninal recording eqipment in a wire connection with the electrical charging device with recorder.

Fig.32 is another functional block diagram of a device complex comprising an suction injector with skin squeezing

35 mechanism, a metabolism measuring device with changeable sleeve with sensor thread (c.p.Fig.47-54) and the respective electronic control unit or programme control.

- 29 -

Fig. 33 is a horizontal section through a jet injector for single drug cartriges using a suction cup. Below, to the left, a pressurized gas stream pump for suction production. Above, to the right, the detail with cartridges for a pulver jet injection in serie. Below, to the right, a detail of the locking mechanism* for switching over to a new injection, if a step *is shown syringe for multiple dosages is used; this is done in an enlarged vertical section along the carriage(910) with the hinged locking

10 bolt, pulled by the tow line(912).

Fig.34 shows spectacles for diagnosis by laser investigation of the anterior eye chamber. Above, the frontal view against such spectacles on a face is demonstrated, in the the longitudinal section of the right half of the device

on the level of the head-band with the singularity of schematic frontal section through the left eye with photo emitter and photo sensor ledges. Below, to the left, a partial plan view under the longitudinal section in the level of the blind visor, quite below an to the right

cross sections through the respective adjusting wheel are shown. To the right, a much enlarged eyeball with a lateral light projection and evaluation for the adjusting of the light ledge for the metabolism measurement, from wich below the left one is shown in further enlarge-

25 ment, both in a frontal view.

Fig.36 schematically shows the detail of two laying pressure springs as pressure donators for two injection cylinders on a horizontal or longitudinal section with operational details.

Fig.36 shows, above, in an enlarged detail on a horizontal or longitudinal section a two chamber injection cylinder, which is emptied by means of a piston driven by pressurized gas.

Below, in a partial horizontal section, another variation of the two-piston-cylinder is shown and quite below, to the right, a similar solution.

Quite below, to the left, a solution is given, in which the two piston are replaced by folded bellows.

Fig. 37 gives an alternative and and completion of a mechanical control gear in a horizontal section.

The enlarged wheel in cross section, below to the right, belonges to the control of a fluid valve. In the middle a variant of an injection cylinder is showen with an influx control for thinning fluid (to the right in a vertical section). To the left, in a horizontal section in the level of the connective strap, the mechanism of the swivelling of the latter is shown over the folded bellows and away

- from it. Below, to the left, a hose or tube brake is illustrated, above in an enlarged horizontal, under that in
 an enlarged vertical section. Below, to the right, a transversal projection of the toothed wheels is given. (The
 latter was above shown in a tipping up).
- 15 Fig.38 shows very enlarged in a horizontal section a solution for a bolting of a operation wheel (or function) in a fixed position.

Fig.38 shows in a horizontal section a special control gear with an additional intermediate gear for a speed

20 reduction.

5

Fig.39 shows a separated metering device driven by two small solenoids, which works agaist wedges of a respective wheel (shown in a rolling up), to transform the thust motion in a rotation for the metering screw. (To the left

25 through an additional intermediate gear for larger amounts of drugs).

Fig.41 shows in an enlargeded and schematic horizontal section with a pressure spring and a lever transfer toward the pressure donator.

30 Fig.42 shows very enlarged a piece of a tape for the data registering with printed out input and measured date and other essential calculatated data.

Fig.43 shows a table for a schematic calculation of necessary insulin quantities by a computer relating to

35 input data (Information page)

Fig.44 supplements the Fig.43 with input data.

Fig.45 supplements the Fig.43 and 44 by calculation data.

Fig. 46 gives a principle set up of an optical skin control using the reflex photometry.

With Fig. 47 begins the demonstration of an supplementing device for providing of a jet injector with metabolism measured values, especially with tissue sugar values. This is done on a somewhat reduced scale in a rolling up on a horizontal or longitudinal sectional view. Above, to the left the top of a sensor bristle bearing sleeve at a raturale size. Below, to the left, an enlarged vertical or cross section for a locking device against the retreat 10 of the bristle, laterally with a partial side view. Fig. 48 is a schematic vertical or cross section through the device of Fig.47. Below, a horizontal or longitudinal section is shown through the detail of the pressure dona-

Fig. 49 shows in an enlarged detail two functional stage of a special push-rotation mechanism for device according to Fig. 48 on a horizontal or longitudinal section. Below, to the left, the four switching positions(A-D) are

schematically detailled projected in a side view. Fig. 50 schematically illustrates a much enlarged sensor capillary and its operation in a horizontal or longitudinal section by hand activated syringes.

Fig.51 gives much enlarged a special sleeve for a sensor bristle and ar additional device for the injecting of it 25 in a horizontal or longitudinal section. Above, to the left, a shortened detail of the sleeve in the stage of being broken off. Quite to the left, a vertical or cross section is shown through this sleeve.

Fig. 52 shows on similar conditions as Fig. 50 the variation of a jet injection of the bristle by pressurized gas. Above in a cross section stacking sheets for the electrical contact with the bristle in two stages. *are shown Fig.52 shows the variation for the introduction of the bristle (enlarged details above to the right) as a drill. Fig.54 to the left a bristle device a a carrier for a small measuring cylinder, to the right, enlarged the reflex optical evaluation. Fig.55 gives a auxiliary device for urin sampling, Fig. 56 an alarm device against low nightly sugar.

- 32 -

5

1.5

20

30

35

ter support.

Detailed description of drawings

Figure 1 is a schematic representation of an injector in the longitudinal section at a scale about of 2 : 1 (where-5 by the nozzle and drug channels are further enlarged). The closing stopper(2) is shoved into the suction cup(1). The area of the nozzle(3) is closed by the china socket with the incandescent wire(4) by means of the sealing ring(5). The leads(6), symbolized with dashed lines, lead to an 10 electric plug and then to the current transformer (not shown). The tissue friendly fluid is also filled into a step syringe(7) as customary in the trades and can be metered by a pressure button (nct shown). The screw cap for the cannula of the step syringe is connected with the 15 cylinder(9) under the piston(10) through the rigid tublet (8). The valve flap(11) is demonstrated during the filling up of the cylinder to make it more visible. The connecting hose(12) over the back valve(13) in the wall of the suction cup is diverted to the folded bellows 20 (14), again for a better representation. The latter is fastened on the housing(16) with the bottom sheet(15); the head sheet(17) of the folded bellows is enlarged by the sclenoid(18) working by drawing and serving the sucking on of the skin. The anchor or rod 25 (19) of the belonging solenoid is shown as pressure donator for the piston in the drug cylinder. The pressure spring (20) symbolizes the backward motion of the archor or rod. The hammer(21) for the plunger of the piston(10) is bent, because the pertaining solenoid lays covered as well as 30 that of the folded bellows. The dashed lines(22) toward the plug for the control device or unit (nct shown)

Figure 2 shows a injection device in a schematically longitudinal section at a scale about of 3:1.

The inner cylinder(24) with the longitudinal millings on its end is shoved into the outer cylinder(23) with the

represent all wires of the solenoids.

nozzle(3). The lower piston with the annular edge milling (25) above glides in the inner cylinder around the central plunger with the end ledge(26, cross section bellow). The plunger can not be drawn out of the central bore(27) of the upper piston in such a way, but it can be shoved 5 in. From both rotation (or disk) valves(28, see Fig.3) orly this is shown in the upper piston, which leads over the hose(29) to the folded bellows with clean water. A branch of the water conducting hose flows together with the channel for the drug, over the rotation or disk valve 10 into the anterior cylinder space. The folded bellows to the right with the tissue friendly fluid inside of the supply cylinder(31) is correspondingly fitted with hoses and valves. Pressurized gas bolster(31) with compressed CO2 promote the emptying of the folded bellows. The 15 strong pressure spring(32) serves as pressure donator for the upper piston, which is supported upwardly against the roof of the housing(16) and downwardly to the piston bowl, shiftable in the housing and bearing centrally the pct(33) which is cut out to the left. 20 The belt(35), which is fastened in the centre of the housing roof, is led through a central bore in the piston bowl and serves for the stabilization (or guiding stabilization) during the motion of the latter. The guiding pin(37), which projectes from the piston bcwl, prevents 25 the axis rotation in the housing slot(36). The piston bowl is lifted for the compression of the strong pressure spring by means of the screw(38), which is guided in the screw of the cross stay(39). A toothed wheel is fastened on the lower end of the 30 screw, in which the wheel is driven by the pinion(40). The latter is shiftable along to the square operation shaft and is held into mesh with the toothed wheel by a kind of guiding disks. After the release bolt(41) is turned through the 35

pinion(42), which works to its toothed wheel, under the -3 -

edge of the piston bowl, the screw is now turned downwards again in its exit position, to allow the relaxation of the strong pressure spring(32).

After the retreat of the release bolt(41), the cut out pct (33) strokes to the upper piston plunger(34), the piston of which is driven downwards and herewith toward the nozzle. The power transfer to the lower piston is achieved over the fluid (tissue friendly or water) between both pistons. When the fluid between the lower piston and the nozzle is expelled to a greater extent, the fluid from the inter-piston space can be emptied through the annular edge or marginal milling(25) on the upper piston and laterally through the lower longitudinal millings on the inner cylinder(24) over the the chamber before the upper piston and the nozzle without an interruption of the beam. After each injection, a maximum chamber respective cylinder filling is effected after a corresponding opening pcsition of the disk-shaped three-way cock over the flexible shaft(43), so as the clean water is filled, near the nozzle, into the lower cylinder by the influence of the pressurized gas bolster(31) and both pistons are lifted. After the three-way cock is closed, the disk valve(28) in the upper piston is opened and the space between the pistons is filled up (The piston strokes are additionally actively lifted in the derivated application examples). The moment of release of the syringe emptying by the screw bolt(41) can be determined by the user. During the preparation for injection, the chamber behind the nozzle is filled up, while it is closed by a lid or closing stopper(see 2,Fig.1) from the folded bellows with the tissue friendly fluid (per- $\mathsf{haps}^{\mathfrak{S}}_{\mathsf{A}}$ physiological salt solution), first, until the lower chamber on the inner cylinder is closed by the lower piston, perhaps relation to the the illustrated position. The drug is transported out of the cartridge through the cannulas or rigid tublets(8) into the space behind the nozzle by the rctation of the micrometer screw(44). The inter-piston

chamber is filled up in an analogue manrer as the clean

5

10

15

20

25

30

water (or drug) after the opening of the disk valve (45, below in the cross section). The sucking of the skin over the suction hose(46) preceeds each injection. (In this case by a larger injection syringe, not shown). As soon as the skin knob touches the three contacts lateral 5 to the nozzle exit -one of these is shown in Fig.8- the operation of the release bolt(41) is activated. The mechanical motion transfer -as it perhaps occurs between the flexible shaft and the toothed wheel(47) for the drug metering and the cross shaft in gear mesh with the 10 former- is omitted and a box(48) for the electric motor and the control gear (which are minimally calculated) is drawn in. From the numberous electric control contacts, only the counter pin(49) and the correlated contact spring (50) on the housing are indicated, which control the drug 15 metering. Figure 3 shows in a plan view on a scale of 2 : 1 a valve (circle) with ar slant lever(line). The latter is shifted between two lock pins(314,315) with a frame(316) with a slot along the bar. (The Fig. demonstrates a 20 possibility of fluid control in a device according to Fig.1 and 2). Figure 4 schematically shows on natural size the control gear of the invention according to Fig.2. A free change between the functions and functional periods have been pro-25 vided in comparison with the solution in DE P 59 25 940.4. The task was solved by operating the work driver for the control pinion between the different operational wheels by a chaine which acts on occasion of a pole change of the motor, shifting against the working phase of the pinion 30 axis. The driving direction is only counteracting on the pinion axis(51) and the motor axis(53) in each case. The rotation direction of axis and chain is respectively inverted on the final phase of the pinion shifting similar as by a tape of a typewriter. The ccupling for the change 3.5 in the switching position is transferred into the axis. The reduction of the rotation speed occurs from the motor - 3k -

axis(53) through the translation toothed wheels(54). The cpupling is effected for the switching over of the motion direction between the main operation wheel(55) and the large toothed wheel(56) through the distance ccupled parallelly shiftable pair of toothed wheels(57) or -for an inversion of motion- over the derivation toothed wheel triade(58).

The latter is demonstrated in its special housing(59), which is shown above in a cross section. The hatching might replace the representation in the depth planes (or cutting). The diagonally hatched wheel halfs show the plane onto mesh which is destinated for the drive of the large wheel(56). The transverse hatched half indicates a middle toothed wheel which reaches with its perpendicularly hatched half the toothed wheel which is destinated to mesh with the main operation wheel. The special housing is slided along to the squre bar(60).

The switching hook(61, in dash-and-dot lines) is taken with with its fork ends on the final phase of the motion of the control pinion. The motor is driven staccato and eventually charged with current under pole changing until control contacts (not shown) record the full meshing of the teeth.

The ratchet toothed wheel are simplificated by the hookes with axle fastening; the belonging ring of ratchet teeth 25 was only indicated. One thoothed wheel is driven from each of both switching aggregates, which both moves the transport wheels of the control chain(52) by a cross drive with toothed (or beveled) wheels. A counter acting ratchet and pawl mechanism, but also here, provides the necessary tun-30 ing. The axis of the conrol pinion has a cross pin inside of the large toothed wheel(56) which is cushioned against both sides and shiftably by lateral pressure influence. The cross pin meshes with a projecting driver edge inside of the bushing bore of the large toothed wheel. The cross 35 pin rotates freely, after the axis is laterally shifted, because the large toothed wheel is secured against lateral

shifting by a fork(65). In such a way a coupling effect occurs. The row of the operational wheels is omitted, to which the control pinion meshes, to one after other; just as little the common axis parallel to the axis(51) of the control pinion is not shown.

Figure 5 shows a cylinder with double piston for the injection similar to that in Fig.2 in the longitudinal section at a scale about of l : 2 (with an exaggeration of the nozzle diameter). The cannulas or rigid tublets(8) 10 terminate from both step syringes (with drug an body friendly fluid) near the nozzle in the cylinder(67). The orifice into the cylinder chamber is closed by the valve flap(11) each to the other. Tissue friendly fluid is also filled into the inter-piston space through the upper pi-15 ston over a hose and the disk valve(28). The valve disk (68), which closes the central bore of the lower piston, is closed by the tension spring(69), that is, pulled near the piston. The valve rod can not be drawn out of the inner bcre(70) in the upper piston (as in Fig.2). The valve 20 disk or cone(68) shows below an insected star-shaped profile for the fluid passage. The lower chamber with the drug is emptied, first, if the upper piston plunger is stroked with pressure by the pressure donator. The plunger over the valve disk(68) on the end of the inner bore(70) 25 finds then resistance on the end of the inner bcre(70) of the upper piston and the valve disk lets the fluid passage centrally free.

30 Figure 6 shows a solution without valve mechanism between the drug and the body friendly fluid for the overpressure injection in an about naturale size in the longitudinal section.

Folded bellows and hose end(71) are replaceable portions which are filled with body pleaceable fluid. After a cover cap on the hose end(not shown), the latter was introduced in the screwing on tube(72). A small lateral opening in

35

the hose was made coinciding with the drug admitting cannula, while following to a marking. The cap(73) is fastened on the screwing-on tube by means of a bayonet clamp.
The tension sheet(75) is in an adhesive connection with
the adjusting screw(74) The latter is screwed back relating to the dosage, while hollow space, produced by the
metering, is filled up from the step syringe which is partially shown. The piezzoelectric sclenoid as pressure donator is approached along the slotted ledge(77) to the cap
(73) and then loaded with current. The folded bellows is
emptied through the nozzle by the three pressure pins(78),
the drug first.

Figure 7 shows, in natural size the preferred position
of the nozzle, to the left, in longitudinal section and to
the right in cross section. This nozzle(3) lies on
the end of the cylinder and laterally in it, so that more
space is disposable for the pressure donator which is also
laterally positioned, in this case a strong pressure
spring(32), in a pocket portable and flat shaped housing.

Figure 8 is a kind of flow chart of an injection device in its totality as a therapeutic system. The injector, which is mainly symbolized by the suction cup(1) is fitted with an optical control device for the aptitude of the puncture area to exclud pathological skin areas. The light beam which is projected from a light source(LED) through fibre bundles is subdivided into two projection areas and two measuring areas. The one of beam(78) projects against the puncture area, the second(79) to an adjacent area. The comparison of both brightness values eventually compared with measured values of the proceeding use- speak for the aptitude of the skin if they are nearly corresponding. The pressure donator(81) is activated over the control part or unit(80). The metering of the drug was taken before with the keys of the control unit under display control. Pin and contact spring(49,50)

5

10

25

30

transmit the related control values with the rotation of the mircrometer screw. Dosages can be input as well from a wire-less transmission part or unit as such or other data can be transmitted from the injector to the transmission-receiver part or unit(83). From there or on the device, glucose measured values can also be input, in such a manner in which a programmed corrrection of the drug amounts, which should be injected, is possible.

10 The drug dosages and other dates can be time proportionally documented mainly by the occasion of the battery charging on the mains.

/The optical skin control is suitably repeated after the injection. In case the fluid beam has not pene-

- 15 trated the skin or not completely, the measured light brightness values differ very from those before the injection caused by fluid reflexes. This lack is reported and registers should the occasion arise. If this lack repeately occurs, the injector is blocked in its function by 20 means of the control part or unit.
 - The arrangement of the three contacts for the "earth circuitry" with the skin is shown in Fig.7.

Figure 9 gives in the longitudinal section an overview over the principal device connection of the singular por-

- 25 tions of the invention, whereby the greatest length is shortened to 70 percent and thereby the suction cup is also accordingly diminished. Above, a correspondingly scaled detail is shown with the representation of the screw(125,c.p.Fig.13) for the thrust of the plunger in-
- 30 side of the drug or insulin cartridge(113). Just above to the right, the detail of the stop knob(270) of the release stop is still shown in the natural size. The latter is operated by a tow-line from the control gear (see Fig.12), to release the movement of the release slide
- 35 (268,below) against the pressure spring(269).

 The latter is displaced by influence of the pressure spring(260) and becomes free, shortly one after the

- other, the locking blocks(847,848) for the pressure donator or springs(261,262) of the cylinder(9) for the injection of drugthinner mixture and of the cylinder for the injection of the thinner(c.p.Fig.17).
- 5 The release slide and the locking blocks are dcubly installed symmetrically as any other functional portions.

 But the same is valid for the sliding screw(352), which is turned out of the screw sleeve(850) by the strong toothed
- 10 under the pressure denators on the roller rail(852) by mεans of the slide carriage(851), so that the pressure donator springs are lifted and tightened(c.p.Fig.17,10). Thε vigorously constructed control gear(279,c.p.Fig.14 in the frontal section) becomes its motion mement over the smaller toothed

wheel on the screw sleeve. A wedge slide(850) is shoved

- 15 wheel(853). The latter is driven from the pinion of the control gear(c.p.Fig.10) over the translation toothed wheels(54) from the motor axis(53). The switching over from the functional block A to the functional block B takes place over the shifting of the switching bar(789) at the last phase
- 20 without a further lifting function of the wedge slides; that serves to the purpose to drive the screw(121) for the insulin metering and additional auxiliary functions (c.p.Fig. 12,13). The already described release functions fall in the initial phase of the functional block A.
- 25 Also in the detail above, the support column(854) is arranged outside of the pressure donators and serves with tow analoguous columns to take up the spring pressure inside of a special frame(c.p.855,Fig.9 below). The connection strap(856, strong lined) serves to the equal power
- 30 transfer from the outer pressure donator(261) to the injection cylinder(9). Two of these three connection straps(266, 267 below) lead, under the just described connection straps, from the screws for the limitation of the metering plunger or piston movement.
- 35 The supplying of the syringe (or injection) cylinder with drug or thinner -after each injection also with water for

cleansing- ensues from the folded bellows for thinner and water (90,190), which are shoved into cylinder, which again on their part are finally connected with an uptake cylinder(858) c.p.Fig.7). The supply of the folded bellows with the over pressure and the suction production are performed from a bag (263) when the lid(260,Fig.13) is lowered. The four tube socket(258) for the uptake of the pressure springs(259) are drawn in. An oval shape of the suction cup (c.p.the detail above) is chosen as variation.

1G The battery(155) and the electronic control unit(80) are still positioned inside the bcx-like housing whereby the wires and hose connections are omitted for lucidity. Only the housing ring(202) is described from the valve for the control of pressurized air and fluids. Construction and function are 15 described more exactly in Fig.11 and 12.

Figure 10 shows in natural size, the longitudinal section of another solution for the switching between functional blockes. Because in this case a switching happens in 20 three different operation wheels, a sliding switch is not necessary for the spooling back of the metering screws. The metering screws are positioned for forward and back motion for functional block B or C, respectively. The free turning toothed wheel with the leaf spring 25 (785) may approach to the pinion(351) through the switching bar(789) -on the final stage of the sliding function of the block A(c.p.Fig.13) - by tightening the pressure spring(495). The forementioned toothed wheel lies in front of the pinion(351) on the mctor axle of ccurse, $^{
m 30}$ in close connexion with the gear transmission or reduction gear. This gear drives with sliding seal on the axis the operating gear wheel (293) for the block A. Because the cam(783) moves into related recess, the preceeding toothed wheel is rotated by the pinion. This drives the operation gear(293) when the pinion is shoved to the right toward the operation gear (790) for the

switching or functional block B. The cross pin(788) of the motor axis is moved and mounted in the (also rotating) flanged socket(786), inside of the coiled groove (787) with three recesses corresponding to the switch position. Each recess offers support, first, against shifting to the right of the motor axis and in the opposite direction after the shifting motion is released. The last backward movement to the left is achieved by the tension spring(784) between the cross stay(791) and the housing wall. As shown in the detail to the left at a scale of about 3:1, the cross pin is restored to a position corresponding to the functional block A after the functional stage B.

The pressure spring(495) is relaxed by releasing the

15 pressure on the switching bar(789). The leaf spring(785) in the recess of the toothed wheel creates a division of the forementioned toothed wheels, so that the nap(783) leaves the pinion. Holding plates(124) can secure connection to further toothed wheels for the transfer of operational functions. The sliding sleeve inside of the motor axis is not drawn.

For variation, the flanged socket(789) can be secured against rotation. The mctor power is then transferred to the pinion from a parallel axis through a gear wheel which is lead with the pinion in a holding plate connection. Thus the pinion(351) like the operating wheel turns freely around the axis.

Figure 11 reproduces, in a longitudinal section at a scale of about 2: 1, the detail of a centrifugally operated switch as described already in Fig.9. The ratched gear wheels in pairs (703,702) and (707,706) were shifted to the left on the sliding switch(717;c.p.Fig.29); thus the metering screws can be spooled back this way. The direction of the motor chooses one of the two. Over a toothed wheel to the roll(699) the drive runs from the gear transmission wheels(54) after the motor over a toothed wheel to

10

the roll(699). The slide(606) which is formed as pin determines the choice of the functional block, as the case may be either in the worm guidance (shaft) of the inner axle(715) -as drawn-

or in the worm groove of the outer cylinder(699).

The slide(606) contains a portion which is permanently magnetic and is held in the roll in a more centripedal position by permanent magnets. With centrifugal power it is pushed with the motor rotating speedily outward into the worm groove guidance of the outer cylinder, in order to rotate the outer cylinder when the end of groove is reached. (During the continuation of the rotation direction, the speed of rotation no longer makes a difference for switching function). The switching situation shown would transfer, with rotations against the worm groove, the power over the inner axle(715) and the toothed wheels and the free-turning axle sleeve(781) over the switching chain(52) to the functional block A for the cannula retreat. If the direction of the motor is changed, it would solely

If the direction of the motor is changed, it would solely alter the direction speed for switching chain slightly. (The motor retardation can be reached through electrical resistance or through an interrupted staccato current supply). With a more speedy run, a power transmission is achieved through the outer cylinder and the wider gear wheel to the gear wheel (701). The gear wheel rotates its axis and, through the axle sleeve(781), the ratchet wheel

(703). The bevel gear wheel (704) is driven over the gear wheel (782) and another gear wheel rotating on the same axle. Thus the bevel gear (709) is driven on the cross axis toward the corresponding metering screw (functional stage B). This happens through a border toothing of the bevel $g \in ar(704)$. The ratchet wheel (702) goes out of function because its cam(783) has left its counterpart on the turn-

ing bevel gear on its axle. The motor turning in opposite direction is transferred by the ratchet wheel(707) in mesh with the toothed wheel(708) over the tube seg-

10

15

20

25

30

ment to the other metering screw. (The thread direction of the metering screws are suitably coordinated against each other in such a way no switching over is necessary on the centrifugally operated switch for changes of metering). With the manual operation of the sliding switch(717), the ratchet wheel(706) is pushed to the left over an annular groove into the axle and has thereby lost its axle mesh.

The symmetric between the periphery of the wheel and the

device wall expanded tension spring(796) can produce a
kind of release point, that is, a delay between the release functions which can be used for the optical skin control.
The leaf spring(797) on a cam of the driving bolt(798) in
a bore of the slide presses the release bolt against the

tooting of the wheel segment. The latter shows there a
locking effect for the influence of the bolt in one direction; the backward movement is brought about then over
power moments of another mechanism (not reffered to here)
which is eventually classed with another functional

block.

Figure 13 shows in about natural size, in a longitudinal section, the detail of a power transfer to a functional block from a mctor (not drawn) and an operation 25 wheel. The operation wheel (792) chosen is specially large and lies under the pinion(800) which is driven from the former. In the demonstrated functional stage, the lateral naps(783) of the pinion approache likewise naps of the toothed wheel (802) firmly connected to the screw (801)30 about which the pinion can rotate. This is done to rotate said toothed wheel(802) and therewith the screw. Holding plates (124) prevent the toothed wheel (80) -which without transfer function can also be a disk- from shifting laterally. The toothed wheel(803), is like a toothed wheel(804), connected with the screw(801) but able 35 to rotate about that. The screwed sleeve(804), in which

the screw(805) projects, is firmly connected with the toothed wheel(803), The plunger for the thrust of the piston in the drug cartridge can be moved directly over the bar(806) which is connected with the screw(805).

Opposite working ratchet wheels(702,703) can overtake the transfer functions for the drive of a metering screw(c.p. Fig.9 in connection with Fig.14) in tooth meshing with the toothed wheels(803,801) for example over flexible 10 shafts.

(The coupling of the latter two with the metering screw is then effected over separated toothed wheels which lay on a common toothed wheel around the metering screw radially offset to their common drive axis as well as the ratchet 15 wheels(707,706). If the pinion(800) is shifted on its screw(801) totally to the right, after the motor has changed its running direction, the naps(792) of the screw(801) mesh with one such on the toothed wheel (803). The latter and therewith the screwed sleeve(804) is rotated now. The 26 screw(805) is now shifted to the right with its rotation preventing linkage(808). The thrust motion of the pinion(802) is transferred over the bifurcated rod(809) of the switching bar(789) while its cross pin(811) engages the corrugated leaf spring(810). The latter, with 25its bar in the pierced socket is therefore shiftable and jointwise connected with the switching bar(789) which has J ning axle stationary on the housing. The pick-off of an additional ratchet wheel rotation is to prevent the transfer of motion functions in the position of the pinion 30(800) meshed with the toothed wheel(802). The function, which in any case, is secured over the corrugate profil of the thread wheel(814) pressed on by a pressure spring against a rotation locking of the former, is coupled off by pulling of the nap disks(815,816) asunder. The nap disk 35(815, or the map wheel) is in axle mesh laterally shiftable to the ratchet wheel. The map disk(816) turns free or the axis and stands in axis contact with the wheel with

corrugated profil preceeding the toothed wheel(814) over the flexible shaft. (The corrugated profil is drawn again below).

5 Figure 14 gives, above, a frontal sectional view immediately behind the housing wall near the motor of device according to Fig.9. The large toothed wheel translation (279) which is driven from the motor through the small toothed wheel(853) causes the analogue sliding screw to the left, in comparison with this to the left, having to be fitted with a counter running thread for this space distribution.

Under that, to the left in the middle, and to the right of this in a longitudinal section, but below in a cross section, a detail is reproduced of the power transfer from the motor axis(51) through the operation wheels(790, 703;707,706) and other propulsion elements.

Figure 15 shows in the longitudinal section in a scale of 2 : 1 a container with folded bellows for thinner 20 (96) and water(190) as a preferred type. The package cylinder has a partition(196, Fig.) which can be shoved with its edge socket against the sealing ring(381) of the lower portion(382) of the container housing. The edge socket is pressed firmly by the pressure of 25 the middle cylinder(393), which again is tightened by the sealing ring(391) against the lid cap(390) which is tightening pressed on by means of the bayonet catch(388). The thinner afflux occurs through a hose with the cannula(385) on the end of the bottom lid(383), which is 30 tightened against the lower portion (382) by the sealing ring(384). The cannula(385) is sealed toward the folded bellows by the elastic plug(394) which is suitably a portion of the folded bellows. The package cylinder (395, detail bellows to the left) for the uptake of the folded 3.5 bellows (90,190) has around the plug(394) a gap or near

the plug a hole(396) for the gas pressure exchange. The lid cap is screwed on by means of the catch hinge (392) as customary in the trade, which deflects out of its longitudinal axis about 90 degrees by spring power and bends laterally. If the socket(397) with outer thread is added around a central recess, as shown in a detail below to the right. the annular plate(398) can be stored in this recess on the annular seal(399). The inner edge of the lid ring (400) presses against the sealing ring(401) on the annular plate. For this inner thread of the lid ring meshes with the outer thread on the socket(397). The sealing rings(384,391) can be omitted in this suitable construction. The bottom lid(383) and the lower portion (382) are then melted into one single portion, as is also done with the middle cylinder(893) and the lid cap(390). The gas apply to the folded bellows occurs separately through the gas afflux sockets(387,388), the fluid is applied through the cannulas. The lid cap(390) is screwed off by means of the catch hinge(392) for the exchange of the package cylinder halves. k calibration difference of the inner cross section (perhaps hexogonal profile in the lower portion with adaptation also of the package cylinder halves) serves to avoid an incorrect supply of thinning fluid and water to the derivation hoses. The adhesive cover foil(404) which protects the hole(396) and the plug (394) against pollution, is to drawn up before use. If, as shown in the detail below to the right, a socket (397) with outern thread is set up at the bottom lid (383), then the annular plate(398) can be left in the annular seal(399) of this depression. The inner edge of the lid ring(400) presses against the sealing ring(401) on the annular plate. An inner thread of the lid ring meshes for this with the outer thread of the socket (397). The sealing rings(384,391) can be omitted for

5

10

15

20

25

30

this suitable construction. Bottom lid(383) and lower portion(382) are then fused to one single portion, as with the middle cylinder(893) and the lid cap(390). The gas supply to the folded bellows occurs separately through the gas admission sockets(387,388), the fluid supply through the cannulas. For an exchange of the package cylinder, the lid cap (390) is screwed off by means of the catch hinge(392) and the drawn out package cylinder, which has left the cannula, is pushed away from the cannula(404). The new package cylinder is pushed into the lower portion(382). A sudden calibre charge between both half of the package cylinder or suitable differences of the inner diameter (perhaps hexonal profil in the lower portion with adaption also of the halfs of the package cylinder) serve to avoid a false supply of thinning fluid and water into the derivation hoses. Before use, one pulls off the adhesive or sticking pro-

tective foil(402), which protects the hole(396) and plug(394) against pollution.

Figure 16 consists of details which explain the composition of the injection cylinder. The half of the horizontal section demonstrates the positional relations in the closing area of the injection cylinder(9) with the connecting stap(267) toward the screw sleeve (857). In the variation, which is shown in the vertical section below of the horizontal section, the screw sleeve does not project up to the roof of the injection cylinder, but it is firmly connected with the latter. The screw(397) is lifted and depressed by the rotation of the flexible shaft(863) and therewith the piston (10) which is connected through a rod with the plate against which the folded bellows or the scaling membrane is screwed together air-tight.

-49 -

5

10

15

20

25

30

bellows and the piston, which compensates the volume displacement in collaboration with the folds of the folded bellows, that is, if the piston is moved and this for a protection of the space under the piston against pollution and entrance of air. (A rinsing sccket for temporary cleansing the inside of the folded bellows is omitted). The connective strap(267) meshes with the thread of the screw(357). As the lower end of the cylinder(9), the opened valve(11) is drawn in with the supply hose for water(29) below it. The connective strap(856) serves the power transmission to the pressure spring(261, detailed in the horizontal section above), for the expulsion of water or the drug injection. The crossed beveled gear wheels, meshing with one another, indicate that the flexible shaft(863) can also be driven-on otherwise. The flap valve(11), which can be also replaced by the customary valve ball, is shown just below in detail in the horizontal section; for the opening of this, the rigid tublet(8) from the drug cartridge and a supply hose for water(29), in both cases lead in this direction to meet there. The detail just above to the right is a vertical section along the section line of the horizontal section detail to the left under that. It shows the joining together of the drug exit out of both adjacent injection cylinders (9,67) in the injection trow (865), the

Water or another fluid is filled-in between the folded

Figure 17 serves, with series A to C, the schematical representation of solutions for the blocking of the pressure springs(261,262) as pressure denators for the injection.

nozzle of which is directed into the suction cup (not

In serie A, the detail around and inside of the pressu-

5

10

15

20

25

30

35

shown).

re springs(261,262) is rectangularly rotated against the representation in Fig.1 and a sleeve is shiftable along the support column(854). But the stop bolt (104), here in pairs, reaches a notch in a support column through the bore of a sleeve for arresting. The support column is clearly or both vertical sections, in the middle, from which the upper one corresponds to the stage with detented springs, but the lower stage to that is tightened. (The tension takes place by shifting under one or any thightened springs clearly visible in Fig. 10). To the left of the forementioned images, one of the release slides (268), which exist in a pair, is shown. The small slide(273) on this can be adjusted with its working slant through a screw of the control gear(c.p.Fig.5 above to the right). The hatched rectangle on the release slide represents the respective contact with the edge projection on the edge (also hatched) of the bridge(866) toward the sleeve with the slidable cross bolt (35). When the edge projection is depressed during the moving past of the release slide, the bridge(866) is also lowered and the bolt releases the depression of the inner bridge arm(867). The inner pressure spring(262) is propped to the latter. But the bolt(35) can leave the annular notch of the inner support column(868) by making a way in the support cclumn of the outern bridge(866). (The functional stages are better read from the representation in The widdle below toward the middle above). The profile of the release slide is evident from the row of hatched cross sections along the respective section lines. To the right on the pressure spring baskets, the stop bolt(104) for the outer pressure spring(261) is marked in. The corresponding distance of the release slide has a wedge formed profiled narrowness (c.p.also the small detail above) for the blocking of the bolt.

5

10

15

20

25

30

the inner pressure spring(262), analogously to the solution (just described) for the outer pressure spring. It is evident from the dashed drawing of the bridge(866) toward the support ring for the pressure spring(262) 5 that this bridge can rise over the latter like a loop, when the springs are tightened and the device lid is closed (c.p.Fig.13). The series B/C more schematically clarifies possibilties for solution with simply lined sketches for 10 holding, as small as possible, the height of the device in the cross section. For this, the pressure springs (261,262), from which only one is outlined, must be tightened and the device lid must be bolted in a lowered condition. The representation is given for A in the 15 middle in the vertical section in about natural size. The cage or the frame(855) nominates structural strenghtenings totally around the pressure springs in connection with the injection cylinder, from which only cylinder(9) here is is shown, and to the suction 20 cup(1), from which roughly half was outlined. The clamp(870) permits the shortening of the height, which corresponds to the lowering of the lid. The wedge slide(274) -with is again mounted in pairsis laterally installed in the lid to B. The bag (257, 25 Fig.13) must respectively be made smaller for this. The wedge slide is shoved away on the tongue formed ledge, which projects downward through a slot in the lid plate of the device housing to the carriage of the sliding screw. The latter has depressed functional 30 stage the end of the hook of the lever(872) and therewith the pressure spring in the shown functional stage. The final bowl of the lever(872) is raised over the knob-like end of the folded bellows of the injection cylinder and is fixed by the stop bclt(104), 35 whereby the countermotion is arrested by a locking device (symbolized by a triangle).

Above to the left, a variant is shown for the blocking of

(The exact locality of the stop can also be determined elsewhere).

On the end of the support column(854), the lever(872) can be tilted on a pivotal axle against the injection cylinder and simultaneously shiftable in the pivotal axle. The lid of the device can now be depressed inside of the free clearance of the clamp(870). When the lid is lifted whilst creating suction on the skin in the suction cup, the stop bolt(104) can be subsequently retrieves.

- The pressure spring(261) relaxes during the reduction of the folded bellows above the injection cylinder, that is to say, in operation of that.
 - The wedge slide(274) is arranged (according to C) on the device bottom. Inside the frame(855), the wedge slide
- lifts, when sliding to the right, the pressure spring (261) into the locking device (not shown). The clamp(870) remains thereby stretched out; the connective strap is lifted together with the support ring(869) while the lid (260) is opened.
- In the middle representation, the lid was depressed, but also again the connective strap(856); the clamp was pushed together and shortended thereby. (The lowest level of the device is reached therewith).
- In the partial stage to the right, the lid was lifted for the suction production and the clamp was tired apart, so that the upper frame portion with the pressure springs was also lifted. First now, but while the skin is sucked or, the filling up the injection cylinder can take place. If not a additional overcoming latch is mounted
- between the connective strap(856) and the connective strap(267,Fig.8). After the pressure springs are released, the functional circulation is again closed to the stage which is closed to the stage which is shown to to the lef:.
- The double intermediate slide(876), which consists of ledges in contact with the spring basket with the ball

bearings(875), extends over the cross bar(877) to the left in the Fig.) in its portion, which runs beneath the release slide. The cross bar(777) is connected with the broad intermediate slide(273). The tow line(978), the middle of three, runs from the bolts(980,9\$1) over the circulation roll(979) to the control gear, so that the intermediate slide, as to the same time also the the outer slide(274) through the other tow lines, can be ccupled off from the double intermediate ledge(876).

- 10 The mechanism for the control of the release delaying for the pressure springs(262) in shown in the vertical or cross section through the final portion of the release ledge(269) and the lateral projection of the intermediate ledge(269; below in the middle).
- The small slide(273) is shiftably on the intermediate slide by a turning screw or the intermediate slide with the follower pin(879). The latter is taken with by the ledge projection(880) of the release slide. Its movement occurs by means of the pressure spring(881) after the re-
- 20 lease stop(760) is activated by the control gear.

 One can see from the frontal section (below to the left)
 in the section direction A B of the longitudinal or horizontal section, that the resilient bclt(882) permit the
 retreat of the release and intermediate ledge, whilst the
- 25 sliding screw(352) takes the wedge slides(274,275) with, because the former has a rigid connection with the wedge slides.

On the sketch (below to the right) one can see, in a vertical or cross section, in which a manner the hinged sup-

- ports(883), which can be hinged in a flexible joint against a erecting spring, absorb the pressure of the pressure spring(261) and transfer is to the release ledge (what is drawn also in the longitudinal section). The release ledge is, about to the half, drawn back to
- $_{
 m 35}$ the left. (But the ledges have a wedge slant on their ends). After the bolts are released, the wedge slides are

then retrieved out from the projection of the pressure springs, which occurs by the sliding screw.

The supports are pushed sidewards by the respective leaf spring(884) on the ledge for the ejection or injection.

5 The analogous fitting of the inner pressure spring(261) was omitted.

With the described device, it is taken into account, that the pressure donator for the injection cylinders broadly exceeds in power the pressure spring(881) for the

10 release slide. An alternative is described in Fig.35 also with an horizontally laying mounting of the pressure springs(261,262). The operational expendidure can be further reduced by a two-chamber injection cylinder adjusted to the load of the device size.

15

Figure 18 schematically shows in both upper figures the raising of the pressure donators for the injection cylinders and their relation to the lid area in a cross or vertical section. Above to the left, an example is drawn for the closing of the pressure spring basket through an oblique lattice net, on which the rolls of the wedges

The lid(260) is lifted by influence of the pressure springs(not shown; 259,Fig.21) in a vertical section

slides find slight resistance.

- through the detail above. The bag(257) for the suction production with the aim to lifting up the skin is enfolded. The pressure springs(261,262) are also released. The wedge slide(274) with the sliding rolls(874) still stands outside of the pressure denators for the injection cylin-
- ders. The stop bolt(104) lays drawn back in the release slide(268), the inner pressure spring(262) is shown to the left, the one for the outer spring(262) to the right. Below the vertical section shows the stage after the wedge slide is moved to the right and the pressuere springs
- 35 are tightened. The stop bolts are now urged in the respective arressting notches and locked by the release slide, which is drawn back before. The lid is lowered and

the bag is compressed under it.

A corresponding representation of a variation of the release of the pressure donators by the wedge slides is given under this detail image in a longitudinal or hori-5 zontal section. The wedge slide(273) for the outer pressure spring(261) is bipartite and surrounds the wedge slide(274) for the inner pressure spring(262). But the above described lattice net is respectively divisioned, so that outer stripes extend between segments of the outer 10 (spring) and the middle stripe leans on a bow segment of the inner pressure spring. The release slide lies ledge formed outside (in pairs), parallelly to the wedge slides.

Figure 19 describes the construction and the function of a valve control for fluids to a scale about of 2 : 1. 15 This is done above in a vertical section, in the middle and below in a horizontal section.

To the left in the vertical section, the segment axis(201) is connected with the base ring(885) and can be rotated $_{
m 20}$ around the housing ring(202), not shown, which is firmly mounted on the housing. The latter containes the fitting sccket of the supply and derivation lines or hoses, the latters from which are drawn in dashed lines. The supply hoses are introduced from the back in the same level as 25 that of the derivation hoses.

On the stage of the left vertical section, the pressurized air stream is set free in the direction of the folded bellows with the thinning fluid or the thinner(90). The thinner correspondingly flows through the valve bcre in the direction of the injection cylinders (9,67).

The discharge for the water is locked in the direction of the injection cylinder. The stage, which is representated to the right, shows the conditions after the turning of the segment axis at ar angle of about 180 degrees. The

 $_{
m 35}$ pressurized air is now able to flow toward the folded bel-

lows(190) with water and the water stream through the lower fluid valve toward the shunt for the rinsing of the injection cylinder.

Under this in the longitudinal section, two opposite facing insections are shown in the base disk or the base ring. The contacts (207,208) for the signal to the electronic control unit are drawn-in on the deepest location which contacts with the rounded spring tongue (drawn to the right) stabilizing the rotation stage. The base ring is rotated by a nap of the saw tooth ledge (886). The latter is moved there and

- opf the saw tooth ledge(886). The latter is moved there and back by a bar in connection with the related functional block (B and C resp.B or C) steered by the control unit. The type of the tooth shaping determines in which running direction the segment axle is turned.
- The lower representation shows a simplificating alternative of the mechanical power transfer (c.p.also Fig.5)

 The bar is replaced by a leaf spring(887) with rounded nap, which engages in insertions of the base ring. The valve segment to the left is cut in a higher level and illustrates
- together the course of the valve bores whereby quarter circle switching turnings are assigned with the possibility of permanent rotation in one direction.

To the right, a pendulum running is assigned. The fluid stream to the injection cylinder(9) through the valve flap

- 25 (11) is achieved, as shown to the right, by the pressurized gas out of the bag of the lid, this stream being introduced there behind tue very reduced folded bellows for thinner (90). The spring biased back valve(888) prevents a damming up up of pressure and essentially facilitates the clos-
- 30 ing of the lid.

The pressure toward the valve flap(11) from the fluids is regulated by the motor velocity, the throttling perhaps by staccato or chopped electrical current supply, in such a manner that the stronger pressure from the drug cartrid-

35 ges hinders the afflux or supply of thinner in case of bigger drug amounts.

Figure 20 gives a kind of block diagramm or flow chart on the functions of a valve, according to Fig. 13, to clarify the air and fluid stream. During the valve stage A, the bag(257) under the lid of 5 the device is compressed. The overpressure through the connective hose(12) closes the back valve(13) in front of $t^{\dagger}e$ suction cup(1), in comparison with this, the back valve(286) was closed. The position of the valve segments, which regulate the supply toward the injection cy-10 cylinders, on the extent of the relieve of the air stream toward the folded bellows for water(190) and the streaming in the hose(29) for water. But because the pressure relief, by the ventilation with valve switching over to the functional stage A, these lines or hoses are pressure-less. 15 (The same purpose can be reached, by omitting the back valve(286), if the filling procedure in the injection cylinders is just finished during lid depression). The

pressure regulation through the back valve(888,Fig.19) is

significant ir this case.

Figure 21 shows in a cross section along the section line C - D of the longitudinal section of Fig.9 the arresting mechanism of the device lid in natural size. The device serves to the air compression for the expulsion of fluids and for section production for sucking the skin. The attachment of the bag(257) above on the lid(260) and below on the covering plate(283) is achieved over a longitudinal ripe profile of the bag in a parallel arrangement, which is shoved in corresponding grooves of the attachment surfaces. The profile is drawn at a distance, to the left, in the form of a dovetail, to the right, meander like. On the base or socket standing on the bottom of the device, the carriage(288) is slidable along the rail(289).

The tension spring(290) prevents that the flanged nozzle (258) can be depressed and with it the lid(260), connected with the nozzle. The cord(291) must be pulled first

by the control gear (functional block A) over the roll (292; flanged nozzle to the left). When the flanged nozzle is depressed against the pressure spring(287; to the right), the border ring(778) of the flanges nozzle hooks onto the carriage(288). The latter is represented with its rail guidance below in detail in a frontal section. A rubber elastic mounting of the plates of the flanged nozzle on the lid represents a lid of kesser-mount(780); in this way a power safety lid closure is rendered possible by unequally (in time) pressing down the flanged nozzles.

Figure 22 shows three solenoids in longitudinal section and in a schematical composition for functional release. Their functional organes come in approximate natural

- size as an alternative solution. The prolongation of the anchor or rod(19) of the pushing solenoid(556) demonstrates its operational direction with dashed lines. The lid mechanism for the suction production was released by the pulling back of the carriage(288) by means of the
- ccrd(291) over the roll(292). Thereby the pressure spring (287) was effective after the movement of the flange noz-zle(258) was released. The tension spring(290) has already brought back the carriage again in its locking position. When a border ring(778) is used as in Fig.21, an inadverte
- lid sinking is not prevented with reventilation of the suction cup.

The solenoid(555) has not yet released the release stop (760) between the front slive and a ledge of the injection carriage(731) and therewith the skin squeezing is not yet achieved. Opposite the sclenoid(556) the detail about the fixation of the tension and pressure spring(8,732) is repeated from Fig. 4. The classed with lock(765) is actually activated after the release stop(760, above) and it should be in an ergaged position for the leaning on the tensioned spring. (The latter are here in a released con-

tensioned spring. (The latter are here in a released condition before the activation of the solenoid(556).

30

Figure 23 shows in a scale about of 2: 1 in a longitudinal section a double working solenoid(563) for several separated release functions.

- The guiding cam(564) serves herefore, which is fastened 5 through the hook(568) with the retaining beam(566) for the partial rotation of the rotary jack(567). The rod of the latter is activated by the angle piece(569) on the cross stay(570) against a spring-loaded power transfer (nct shown) to a operation organ. The annular sleeve(571) is
- 10 moved under the cross stay on the prolongated anchor or rod(19) with the sclenoid activity. The up and down motion is simultaneously turned over in a partial rotation of the annular sleeve through a zig-zag groove on the inside of the annular sleeve by the guiding pin(542) on the prolon-
- 15 gated sclenoid rod. The ring (plate) with the small(574) and large(575) sector slot is fastened on the annular sleeve. The small sector slot can pass along the angle of the angle piece(569), if the respective return position is reached. A forther rotation lockes the return of the cross
- 20 stay urder the influence of the tension spring(572) on the cross beam(573). As soon as the large sector slot permits the angle to pass, a releas function is operated by the tow line(303). Further operating bars(576,577) can be activated, one after the other, by the partial sectors under
- 25 the annular sleeve. Pushing functions are possible as well through a swiveling angle piece resp. a cross pin on the rotation iack(567) as tension functions (by the cross pin on the rotary iack or the grasping through the sector slots(574,575)). The slots can be adjusted in such a man-
- 30 ner, that the release of the return of the angle piece (569) by its tension spring occurs in a shorter interval after an operation stroke by the solenoid as a second stroke of the latter (because of its response latency).
- 35 Figure 24 shows at a scale 2 : 1 a toothed wheel with electrical record and a clearance of motion, as it can be used mainly for operation gear wheels, the operation

function of which works only to one direction. The insulin metering is an example of this. The axle(223) is surrounded from the electrical noconducting isolating ring(224). The drive pin(225) projects from the axle sleeve(230) and pushes against the stop pin(226) which is roofed by the spring tongue(227). To the right of the frontal section, a longitudinal section.

To the right of the frontal section, a longitudinal secttion is shown in the section line A - B. The toothed wheel cames between the leaf springs(228,229) on shifting laterally. The spring tongue(227) is suitable then, when drive peg is adjacent to the toothed wheel; the side, turned to the latter, of the drive pin must be isolated then (c.p.cross section B - C above). The current flow over the axle toward the leaf springs(228,229) can be tapped. As suitable a tooth or any teeth either can be isolated or not; the no-isolated allows contact with one or both leaf springs(228,229) that the number of rotations are controlled. The current conduction over the drive pin perhaps to one or any no-isolated teeth(231) on the counter side of the drive pin allows the free clearance of the gear, perhaps on a function less passage of

the control toothed wheel or pinion to the other operat-

Figure 25 shows, above in a vertical section to a scale of 2: 1 and below in cross section in a scale of 1: 1, two lid blinds for the nczzle, which, positioned or their own radia, are moved past the nozzle through the suction cup roof.

(Below in the cross section, the pressure donator(81) and the injection cylinder(9) are omitted, but also the suction cup(1) with the edge rounded for sliding past the skin, the back valve(13) and the throttle valve(578) in the ventilation channel and the skin, which is raised up under the influence of suction and drawn with dashed-

- 61 -

5

1.G

15

20

30

35

ing wheels.

and-dotted lines.

The segment like shaped covering sleeve(337) with the heating wire for the germs killing at the area of nozzle is yet drawn away (below in the horizontal section) from its position over and behind the lid blind(309, above in the verti-5 cal section) by the toothed wheel(582) and the inner axle through the section cup roof. The follower pin(586), which projects from the toothed wheel, now strokes (as shown in the vertical section above) against the radial slide and has tightened the tension spring(588) between the fastening ang- $_{10}$ le(590) on the rotation disk(589) and the radial slide. The rotation disk is connected with the swivel arm(584) for the segment of the lid blind(309) through the axle sleeve(585). (The axle sleeve is tightened in the bore of the suction cup roof and toward the axis(591) for the swivel arm(584). The 15 sectoral shifting of the segment of the cover sleeve (337) has taken place immediately before the suction is introduced in the suction cun. The tightening of the tension spring(588) is increased immediately before the injection to such an extent, that the ball stop(592), which is resilient against 26 the suction cup roof, breaks out of a stop notch. The segment of the lid blind(309), which is not turned away from the nozzle, now activates the injection procedure. (The injection beam into the suction cup is shown with fine dashed lines above in the vertical section). 25 For reventilation, the air escape can be activated laterally urder the back valve through the opening of the throttle valve(578) by a lateral air channel(593).

Figure 26 gives an alternative solution for nozzle ccv30 ering outside of injection of drugs or ejection of water
for cleansing. These covers are thereby lifted
before the pressure donator is activated.
Above, a vertical section through the suction cup is shown
to a scale 2: 1 of, under this to the left, a horizontal
35 section to the scale of 1: 1 in the level A - B (also in
the level of the beam) of the vertical section as a detail
of the ervirons of the injection cylinder. Below to the right,

the surroundings of the nozzle is more illustrated in a scale about of 3:1.

The cross stay(554) is lefted along the grooved rail(595) by the skin, which raises under the influence of suction. 5The sectoral like cover sleeve(337) with its heating wire loop together with the leads is also thereby lifted with photo emitter and photo sensor with leads from the suction cup roof. (In the detail below to the right, it is in each case only one lead end demonstrated and the course of the 10leads inside of the suction cup in the longitudinal section above). The light beam which controls the skin condition, for example, projects perpendicularly on the inside of the sector of the lid blind(597).

The cover sleeve(337) has the passage(597) for leading 15past of the mirror nose and the light passage. The equipment for the reventilation corresponds to that of Fig.27. The photo emitter(580) and the photo sensor(581) is drawn-in with its laser ray connection for the injury free metabolism measurement, mainly for glucose, without lead connections

- 20 and the respective analytic apparatus. Relating procedures were filed to the patent in the Federal Republic, first, from Nils Kaiser (Untergarching) and Arnold Mueller (Ulm). As alternative for the heating wire(239) in the blind (below), the heating wire was put around the nozzle above.
- 25 (The latters can be observed on the dashed-dotted drawn fluid beam). As alternative for the optical control, light conducting fibres (982,983) are drawn-in below near the nozzlefrom the emitter to the sensor.

The wedge(334) on the release bar effects, if it is de-30 pressed (or in other cases, if it is lifted), a shifting of the strap of the lid blind on the guiding slot(558) and therewith the release of nozzle (3, which is outsized).

Figure 27 reproduces, above in a vertical section, below in 35 the longitudinal section to a scale 2 : 1 a suction cup with a blind(889) for the nozzle(3), which is shoved upwards

by the skin itself while it enters into the suction cup.

The exit of the injection beam out of the nozzle of the injection cylinder(9) is marked with dashed-and-dotted lines. The annular blind(889) has bent hooked projections(890) toward the skin and a weak replacement spring, which works as a pressure spring (that is to say at least three on the circle circumference), supporting the laying of the blind on the suction cup edge.

- As shown in Fig.26, the blind ring can have a perpendicular 10 rail conduction in the suction cup; it can receive photo measuring devices. But also an electrical lead can conduct to the heating wire(239), to liberate the blind itself and the suction cup edge again and again from pathological germs. The material of the blind must be chosen with appro-15 priate heat resistant quality; perhaps coated here ard there with teflon. The ring contact with the section cup edge can be intensified by magnet inlets. But also the form and the material shaping can be useful to promote the sudden jerking of the blind, if the suction cup is pressed 20 against the skin. But the resistance of the hook projections during the raising of the skin by suction can also support such an effect that the nozzle is quickly closed by the skin. The blind ring can be constructed smaller than it is drawn and be additionally supported in its raising by cross *can 25 stavs(594). The air derivation occurs through the connective hose(12) to the vaccuum source.
 - Figure 28 shows an optical skin control mechanism inside of the suction cup (above in a natural size) with (eventually) controllable nozzle valve(378).

 The injection cylinder(9) projects under the pressure donator(81, in dashed line because it lays behind) into the suction cup(1) being sectioned-on behind).

 The transparent glass or plastic measuring window(579) lies immediately under the nozzle(3). Beside, -for exam-

- 64 -

ple, the area of the suction cup rim, - the light measuring arrangement with light emitter(580) and light receiver(581) are shown.

Below the detail of the optical control device is repeat-5 ed at a scale of 5 : 1. The skin fields or pattern are lattice like drawn under the window(579), additionally the light beam from the light emitter (or transmitter, as from a LED or laser) through the window, there reflected from a concave edge against the skin back over its concave edge into the light receiver. From the cable connections are reproduced in each case only two on its final segment. During the raising of the skin, the skin patterns are drawn past the window. The computer classifies, after the stand-still of this motion out of the stored skin portion measuring fields the over the nozzle resp. over the diaphmagm the area of the nczzle (or cannula if used) laying measuring field with the corresponding light exstinctions considering the speed of skin raising. (A task which is performed today by any PC-CAD-programme analogously). It can be determined in such a manner by the breaking off of the functional running without injection before the lid diaphragma is opened (or a cannula is pierced, if any). In the case of more imparts of pigments or in other kinds of imparts from comparatively normalskin, deviating skin area -at a spotted surface pattern (perhaps with akne or with freckles) - the skin knob .can be lowered slightly by the opening of the narrowly placed nozzle valve(578) and the puncture can be performed at the moment in which a probable healthy skin area lies over the (injection) nczzle (or cannula if used).

Figure 29 shows a plan view of the preferred form of the device (c.p.Fig.9) after the arrangement of the inner mechanical equipment is concised. The position of the suction cup(1) and the insulin cartridges(113,114) as well as of any cannulas (or sleeves with sensor threads, Fig. 47-54) is shown through the break off, above which

10

15

20

25

30

the subsequent described surface equipment is continued. A sensor contact(817) corresponds to each circle on the rows of the device surface, with said sensor contact(817) reporting the finger contact, in the kind of earth fault to the control unit, and activates a 5 switch. The touching is suitably confirmed over a light scurce, which makes the touching point luminous. For this aim, a pin with flasky colour face can be but roofed at the end by a transparent pot(818) which is depressed against a spring and catches with an edge ring behind the 10 ledge(819), lightening up the colour field during its fixing. (Detail above to the right in a frontal section). The ledge(819) has regular edges recesses, as the cross clears under the detail. Suches ledges can extend now along in each a row and can be operated, mounted at a ccm-17 mon spring resilient frame, so that all pots are released for the upward movement. A similar (perhaps inverse functioning) device renders possible the reading out of inputs also to the blind. Display windows -perhaps as a fluid display- contain a time scale which moves from abo-20 ve to bεlow. The patient ins now atle to report, coordinated to the intended meal, also with regard to ites glucose content, to the control unit by means of the influence of the pressure against the sensor contacts. Because the glucose content of the food is reduced during 25 the progress of the digestion, an approximate triangle fiqure with a large base below comes up to this operation. The basis breadth should be indicated on a larger recording tape thereby with higher glucose and starch content of the food. The precision of this programming can be auxi-30 liarily improved by computer, but essentially that can be e>ercised mainly with the control of the results indicated on a recording tape(see below). The extent of planned body activities is expressed, time related, in Watts on lateral rectangles by contact operation. Exiting from 3.5 the actual measured glucose tissue level and considering the input of personal insulin working constants and

the working profiles of the used insulins, the height and the mixing relation of the insulins is now explored by the computer and the decreasing triangle of these is brought about in concruence with that, which the patient has drawn in; if it is necessary to warn against absurdities of the programming, the injection is performed according the dosage. For example, an input of the food and labour charge is drawn-in in dash-and-dot lines, formed as two triangles and two rectangles between the sensor contacts. To the right, the virtual image of the derivated computer operation is shown, The programme inputs are drawn in dashed lines, whereas the computing results are reproduced in dash-and-dot lines. Dangerous outline breakdowns(821) induce the computer to warning signals while it marks the date in case the gape can be closed orly with disproportionate dosage alterations. The patient shall then complete the food or take a measurement at the questionable date. This extension of the possibilities for programming exceeding the condition of PCT/DE85/00313 on 1985, now allows desage adaption also of the depot insulin adjust-

ed to the planned routines of the day by the patient and, therewith, a more independent life style.

The dosage intending special program blocks adapted to the course of day (sport or bureau day) and the fixa-25 tion for laying down of steps for emancipation of the patient related to his ocoperation are, of course, the further fundament.

One of any given example for a trial and error definition of the constant or multiplication factor for a dosage of immediatiely working insulin, may be proposed: 60 min. after a meal with 3 BE (bread units) and 90 min. after the injection of 10 Units insulin the measured value <100 mg% may stand for K = 0.5, <120 mg%

for K = 1; <140 mg% for k = 2; <160 mg% for K = 3; <180 mg%35 K = 4. For this aim (of programming) the hand switch wheels(822) are arranged along the device well(16) to

10

15

20

adjust, correlated to their scales, sensivity constants (K), death (or warning) point with regard of the glucose content and correcting frame as well as program blocks. It shall still be mentioned that the device could be used also only for diagnostic aim (also without injection), perhaps for the control of substances excreted by the kidneys. But the device could serve exceptionally for injection use, when accordingly simplified, for example, for the application of heparine. The sliding switch(717) on its rail guidance is still drawn-in above (c.p.Fig.9). Figure 30 gives a detail of the programming board on the broadside of the device at a scale 2 : 1 above in a vertical section along the alongside of the device and below in a corresponding horizontal section. The example makes more precise the solution to Fig.29 and is a refinement of that. Gver the cover plate(283) a further lid (219) is mounted on the side wall of the device detachatle with its marginal ledge. The plug(220) stands in rows with corresponding holes on the lid(21)) into which the pags project. The hole is so large, that the transparent cap or pct(818) on the peg(220) is downwardly shiftable against the wire or leaf spring(221). Or account of the leaf spring(222) between the adjacent ledges(819) the latter makes way for the slant of the annular collar on the end of the cap or pct(818) and the latter on the steep flank of their annular collar in a depressed position. A flashy (perhaps green) colour coat on the upperside of the peg(220) is visible through the pot. In case the input with pressure up on the pot(818) is cancelled, the key(293) must be pressed therefore against the pressure spring in the guide clamp(294) of the lid border or rim. The ledges(819) have regularly spaced incisions or notches(295), so that all caps or pots of the row return upwardly to the O-position by 35 means of their wire ore leaf springs(221) if the key is

5

10

15

20

25

pressed. The movement of the ledges is made possible by their recess(296,above). Each ledge is secured against rotation by the profil nose(297). The profil nose surpasses the key sheet and can be turned between both pins (298,299). After the glock-wise rotation up to the stop, the profil nose can disappear in the slot(313) of the lid rim.

about of 1: 4, a device complex consisting of the housing of a pressure jet suction injector with the battery supply(255) and the space for the installation of the chip equipment as the electrical control unit(80) for mass production. For small series, the flat stacking encasement is plugged into corresponding sockets of the housing by means of the contact and coupling pins(679) with electronic equipment, perhaps a micro processor with the related storing elements.

To the right of the injector housing, the encasement of a charging device(677) is shown with its double plug to the mains and the lead connections to the socket(682) in the encasement of the electronic control unit, the

The course in the functional blocks of a device according to Fig.1 -13 can correlate to the approximate following scheme. (Thereby +++ indicates the rotation or shifting to the right, and --- the same effect to the left):

I ++++ suction+ejection release/tightening of the springs

for the pressure donator/tightening of
the release spring

---- switching to II + piston retreat dosage 2/
release of the springs for the release slide
/delaying slide back to 0/switching to II
I++++screwing back of dosage 1--idling++additional thinging

35 II++++screwing back of dcsage 1--idling++additional thinning/ metering dosage 1

---- idling/ delaying slide/ switching to I]I -69 -

5

III ++++ idling -- idling ++ additional thinning/dosage 2

---- fluid switching (between thinner and water) / delaying slide / switching to I

Figure 32 is a schematical functional set-up of the electric circuit control. The operation of the hand switch If the three sensor contacts on the rim of the suction cup(1) report earth fault(301), fed from the battery (255), effects the current to interrogate in the electronic control unit (e.c.u.300), if a locking or prohibition is programmed there. Influencing is only possible then over a hand switch wheel(822) or over the key board on the lid(219). The next interrogation relates to the presence of a cannula before the funnel of the suction cup.

The sleeves (691) for cannulas are suitably coated with metal so that the solenoid(155) on the groove before the funnel to the suction cup can escape. The conductive bridge, which connects the spring clamps(152) between the cannula on the groove and the reighbouring one (691) is tapped over the contact on the groove and the contact spring for that. The current stream between the groove and the contact spring confirm the presence of a sleeve with cannula. The counter or computer is able to ascertain from the total amount of cannulas and from the distance of each cannula from the spring clamps, which close the chain, and from the frequence of use, if a cannula is yet an unused one. From the e.c.u.(300), the command starts for the opening of the seat valve(134). After this, the question ensues over the light emitter (580) and the light receiver(581), rather the skin, is on the suction cup rim from inside. Light source and sensor can be directly mounted in the funnel of the suction cup; but they also can admit there light conducting fibres and receive the latters(c.p.Fig.54). The measuring sig-

nals are measured at least on two adjacent skin areas

5

10

15

20

25

(spots) and the grey-values can be compared one with other, as Fig.46 demonstrates.

The squeezing mechanism for the skin is released then. The sliding sheets(9) have a slight deflection of their edges downwardly to the skin. They have a sharp bottom edges and a cross rippling of the edge region. One may eventually renounce the application of suction before the squeezing of the skin.

Before the suction release in the functional stage B of the hammer(121) the release of the stage A is due to change a used cannula and to seal the funnel to the suction cup with a new one.

The interrogation from the light emitter and sensor takes place again by the e.c.u.(300) to control the scheduled prick-in area. If the differences of measured values are too high, a command from the e.c.u.(300) to the motor shall be emitted to produce suction again for a itineration of the measurements while the skin is yet slightly drawn back.

Figure 33 gives a horizontal section through a device for injection, which can be operated with single drug cartridges and can be used by several persons without the danger of transferring infection transfer. The scale is 1: 1. Below to the left, the appropriate gas jet pump (442) is represented.

The gas jet or beam pump stands in connection with the pressure control throttle after a pressurized gas capsule, perhaps with nitrogen, carbonic acid, or oxygen, through the supply hose(499) as well as the pressurized gas hose(893,894). The injector itself is held together from a ledge frame(895). This pertains to the base plate (15) with the cylinders for the battery(255, not shown), which are distributed in two single pieces, surrounding the traction solenoid(555) up to the base plate(896) which is a little shortened and therefore drawn as if broken off. In the middle of the edge to the left of this base plate, a tube formed sccket(897) for the in-

- 71-

30

3.5

5

10

jection cylinder is inserted. The injection cylinder builds a detachable portion together with the suction cup(1), the gas jet pump(442) and the electronic control unit(80) which are closed together by the bridges 5 (898,899,900). But this portion remains in a certain loose unit with the base plate through the hose connections and the dashed drawn electrical wires between the control unit and the battery, respectively the solenoid. The drug or insulin cartridge(113) itself has the nozzle(3) for the injection on its free end. The cartridge can be grasped on its 10 edge which surrounds the injection cylinder, and whereby the cartridge is bolted in both bayonet catches(901,902) from which the first is mainly essential and works against the sealing ring toward the suction cup. The base plate is interrupted by slanted profile slot(903), the edge of which 15 is designed step-like , the reverse edge of the profile slot having a recess (904) facing to each step level. Between the base plate(15) and the sliding ledge(905), the folded bellows is inserted, again in pairs. As pressure denator this is preferably a metal folded bellows. The 20 sliding ledge can be moved in the interstice between the base plate(896) in front and the ledge frame(895), and $b \in hind$ together with the plunger (906), which is fastened onto the sliding ledge. This moment is impeded by the peg '907), which leans against the step of the profile slot and 25 which can be shoved with the carriage (910) on the rail (906)of the sliding ledge cross to the motion direction of the latter by the knob(909). The carriage can be impeded in this shifting by the edge of a tongue, which is connected with the carriage through the hinge (911). This happens if 30 the tow line(912) is shortened against a resilient spring by the rod of the traction solenoid(555), because one end of the tow line is fixed on the mentioned tongue. The suction cup, the gas jet pump, and the electronic control unit are connected with the ledge frame by the clamps which 35 are sketched with 913,914. The handle(915) is elevated from the base plate with circular cross section and bends them as if on a trowel to the

- 7**2** -

solenoid. It can be clasped with four fingers, while the thumb shifts the knob(909). The carriage under the knob is partially drawn below in the vertical section to a scale of 2 : 1 .

5 On the detail below to the left, the construction of a gas jet pump is shown to about natural size in a vertical section. The gas stream runs from the supply hose(449) of the pressure control throttle through the exit openings on the point of the high valve cone(505) into the nczzle 1.0 chamber (500). Air is dragged along out from the suckingon chamber(502) and thereby air is sucked on from the connective hose(12) to the suction cup(1), at the distance to the entrance into the funnel(505). The resilient back valve(13) prevents the air from entering into the 1.5 suction cup, after the jet pump is turned off. The latter is fitted with a suction switch to interrupt the gas admission stream, when sufficient negative pressure exists. This occurs after an appropriate negative pressure is dammed up behind the elastic membrane (503) through the 20 suction lead(506) in connection with the connective hose

(12) from the sucking-on chamber. A central pin is connected with the valve cone through the pierced support wall(504). If the suction essen-

tially exceeds the intensity which is needed for the sucking of the skin the elastic membrane (503) and raises with it the valve cone. The latter closes at its end the lateral gas inlet openings and halts thereby the gas supply to the nozzle chamber (500). As a variant, the cone pin, which projects from the membrane can also

30 reach up beyond the nczzle chamber, and it can stop the gas beam there (not shown). The suction damming up inside the suction cup can be recorded by the appropriate contacts, which are moved by suction, to the control unit(80) and from there a signal can be re-

35 leased. The same is practical, if the optical control device for the skin confirms from the segment of the

cover sleeve(337) unobjectionably anatomical conditions on the injection area. (As described in Fig. 25-28,53,54) the control unit releases the injection nozzle free.

A small folded bellows(916) is beared forward to the piston(10) with the tissue friendly rinsing fluid or thinner. The latter is pressed against a annular edge behind the nozzle opening and has a prepared breaking zone. When the knob(969), caused by the gas supply into the folded bellows(432), is moved downwards and release the mction of the plunger(906), the rinsing fluid is pressed through the skin (after the drug and the destruction of the prepared breaking zone) without interruption of the beam.

If the drug ampule or cartridge is destined for use as a step syringe, the small folded bellows(916) with rinsing fluid is omitted. The knob(909) is then moved upwards (that would mean in the drawing: to the right) and delivers the appropriate partial quantity of the drug through the nozzle(3), which runs obliquely in this case, into the upper skin with the formation of a skin bladder or lump there.

The suction cup is thereby placed on anew for each bladder. The heating of an incandescent wire around the suction cup must be recommended for the derm extermination before changing to another user.

Above to the left, rectangularly turned toward the injection device in the middle, the detail of a variant for the powder injection is shown in the horizontal section.

The drug powder (984) is stored inside the cartridge (985), protected by protective membranes (986,987) against the skin (986) and behind (987) it. The cartridge is tied past in a chain with thread connection before the suction cup (1). The membrane (986) is destroyed in the trough or nap depression (988) with the heated pin. When the cartridge is further transported to the funnel, it is pressed and sealed by the pressure tube (989) into the funnel.

- 74 -

5

10

25

30

After the posterior membrane is destroyed by heating, the appropriate powder is shot through the skin by a gas stroke. An addition of dosages with or without displacement of the skin is possible, while the funnel orifice into the suction cup is tightened intermittently by the cover sleeves (337).

- Figure 34 demonstrates spectacles for diagnosis, as they are suitable for metabolism measurement, preferably for the measurement of glucose in the anterior eye chamber. Above, a frontal view is shown, in a scale about of 1:1 after the carrier beam(929) in which the device appears over forehead, nose, and ears, and it seems to be set up
- around the eyes. Below the left eye, the arrangement of emitters and sensors resp. of the mirror ledge is shown with dashed drawn light ray way to the cornea dome, which is protuberant in the center, and to the eyeball curve whereby the eyelids are omitted.
- 20 To the left, in the middle, a horizontal section in the level of the handle-like carrier beam(928) is drawn.

 Below still further details are described. (Projections lines for the attachment of the different portions for the different views are given dashed-and-dotted).
- The spectacles are installed here for measurement on the right eye. The overlapping of the portions of the head-band (930) and its spring clamp are not shown, because this equipment is known from every support device for medical frontal specula. The bows, which project up to behind the
- eyes allow an additional fixation on the heighth, the nose bridge(931) securs against a lateral shifting. The electrical motor(478) lies inside of the electronic control unit(80) on the bow toward the ear to the right, the battery(255) lies on the bow to the left ear. The adjusting
- 35 wheels(932,933,934) are fastened by projecting angles. From them, the distance screws are adjusted in the depth

through flexible shafts (which are only drawn in its initial portions) and through the connective strap of the carrier beam(928, in the middle). Bclsters(938) can be shoved up to its curved knobs. The support of the bolster(937) on the end of the distance screw(935) between the frontal bone and the eyeball on the upperlid ccrresponds to the adjusting of the adjusting wheel (939). The adjusting screw serves also to the support by means of the bolster(938) on the lower lid between the cheek-bone and the eyball. (The belonging distance screw lies below the distance screw(935) and is therefore not shown). It is driven by a threat on the adjusting wheel (933) through the toothed wheel(944) and has also a counter running thread against the distance screw(935). The distance screw(936) is operated on the adjusting screw (933) and the position of the bolster(939) between the corner of the eye, the nose bone, and the frontal bone is therewith destined. (Under the distance screw(935), the eyeball is drawn, and this dashed for its always not visible portion. It corresponds (that is to say: their standing for) to the springs and the distance screws, that the rounded end of those, or which these pressure springs lean, are carried from the respective inner pin and is projected in such a manner against the face; this singularity is omitted in the drawing). The distance screw(932) promotes the curved bolster(940), which is put against the bow of the cheek-bone bow from outwards. The distance screw(941) is driven through the screw sleeve (942) and the transmission toothed wheels(54) by the motor axis(53). This distance screw(941) brings the frame(944) in a different distance from the eye by means of the angle bar (949) with the rail below the outer carrier beam (928). The inner rail(945) extends on and under the parallel portion of the carrier beam(929) into the direction of the headband (c.p.the lower detail in a horizontal section). The blind - 76 -

10

15

20

25

30

visor(947) is tipped up between the double hinged join (946) before the metabolism measurement.

Both light leages (951,952) are thereby erected toward the eyeball. A light scurce (not shown) is directed against the eye through the central hole of the blind visor as assistance for fixation. The adjusting wheel (949) on the frame (944) permits an adjusting in the heighth of the blind visor, the adjusting wheel (949) being therefore coupled through a flexible shaft to the adjusting wheel (950)

10 (c.p. the detail of the adjusting wheel(948) in the frontal section, below, quite to the left, and the detail of the adjusting wheel(950), just to the right).

The light ledges, which are shown under the left eye, are again stressed below in its position toward the eye-

- ball in a scale of 2: 1. The light ledge(952) might serve as a broadly and drawn with dashed lines radiating light source (the light is her drawn as dark hatching). If one has looked toward the fixation light of the blind visor, the cornea projects a shadow to the light ledge(951),
- along the length of which sensors are distributed.

 The optimal depth adjusting for the metabolism measurement can be adjusted by rotation on the electrical motor(478) according to the distribution of the measured values which are recorded from the electronic control

25 unit.

If a second such light ledge arrangement is present, turned about a right angle, the adjusting of the frame (944) on the adjusting screws(948,950,953) can be performed automatically with the help of the computer and

- the mctor, and with the interpolation of a respective control gear. During the putting on of the spectacles for diagnosis, the blind visor and the light ledges suitable are still held in distance from the eye, and they are carefully approached to the latter.
- Just to the left, the light ledge(951) is drawn again in scale of 4 : 1 from above, to demonstrate the example of

a glucose measurement. A light beam might be projected from the photo emitter(580) to the opposite positioned light ledge (not shown) and it might be reflected by a small mirror(955) to a mirror of the light ledge(580). This proce-5dure can be repetite along the light ledge, but also on a single measuring straigth line, then proportionally to the duration of the light flash. The photo receiver (581) is able to ascertaine the contents of glucose on the basis of standard comparisons of the differences of the measured 10 values. One can utilize either the alteration of the polarization plane by sugar or the alteration of the dispersion angle of laser light or other known methods. Of course, the spectacles for diagnosis can also abe installed exchangeable for the other eye or can be elaborated for both eyes. 15 The electrical-electronic control unit(80), suitably containing a recording device, an alarm -clock or flashes-, a memory for the ascertained measured values, and a transmitter which works in the directiuon to the injector or to the common or system recording device, which unit is, 20 as the rule, connected with the charging device (on the mains). The electrical wires between the control unit(80), the light source on the blind visor(947) and to the battery(255) are drawn not resp. interrupted.

25 Figure 35 shows schematically the detail of two pressure donators by means of laying pressure springs(261,262), which are parallel to the device. (The other functional portions are omitted; a broadening of the injector could be the result of this solution in its total conception).

30 Nevertheless, the pressure springs(261,262) can be connected with auxiliary spring segments(962,963) through cross stays(960,961), which are fastened on rigid connective bars, so as the vacant spaces in the device can be used.(The auxiliary spring segments were diminished to about 8 : 1 be-

in row can be productive for this, because the level or ex-

tent of the piston(10) stroke figures at between 10 and 20 mm totally.

The power transfer occurs through both angle bars(964,965), to which final plates the pressure springs(261,262) support respective to which final plates the connective bars(958, 959) are fastened. The counter bearing of the pressure springs(261,262) is built by appropriate strengthening of the housing wall(16).

The pressure syringes are tightened completely through the 10 sliding screws(352) by the rotation of the screw sleeve(850). Both solutions for the injection cylinder(9) are analogously valid for the injection cylinder(87). The locking of the bars occurs by the release slide(268), which is urged away from

 $_{15}$ the cam(966) on its roof-like wedge slant(961) in the described functional stage.

The annular groomes as locking insertions on the angle bars are shifted to the left relating to the piston lowering. The release wheel (968) therefore operates an eccentric lever.

- 20 which brings the release slide again in a locking position toward the angle bars with the annular grooves, which are shoved to the right. This happens over that cam(966) and the forementioned wedge slant on the counter side of the release
- 25 slide. Tension springs and tension spring segments in row are also able to serve as a pressure donator for the injection cylinders, of the power transferring elements are correspondingly adapted. (The small stop fork to the left of the release wheel (966), which is operated by a tow line.
- 30 works against the eccentric fastening axis of the eccentric lever, if its spring serves as releasing power). The symmetrically arranged springs and spring elements can be connected with a common angle bar, if a single injection cylinder with a two-chamber system is chosen as describ-
- 35 ed in Fig.36. In this case the order of symmetry of the distribution of spring power is invalid.

Figure 36 shows in a horizontal section, through the detail of an injection cylinder according to the two-chamber system, an alternative for the sclution of the problem of the cleansing of the injection channel by thinning fluid on a 5 scale 2 : 1 .

An oval or square housing(431) with partition(430) for the clinging of the folded bellows(432) serves as pressure donators for the double piston arrangement inside the injection cylinder. The folded bellows(432) centrally contains a pas-

- 10 sage for the screw(435), the thread-less portions in the hammer bcre(70), which does not completely continues. The latter belongs to the upper piston and has a disk-like enlargement or collar on its end. The screw is driven by a pinion in the thread of the partition(430) by means of the
- 15 tcothed wheel(438). The pinion les over this in a sheet connection and is driven along by the screw, if the this is depressed.

The latter is connected with the pair of toothed wheels(441, 442) through the flexible shaft(439). The pair of toothed 20wheels, runing indepently, is also rotated by the operating toothed wheels for the metering of both insulin sorts. But this occurs in both rotational directions of the pinion by means of an special operating toothed wheel(441).

(The toothed wheel(443) is a portion of the control gear, 25 not further discussed here). The stored pressure in the

folded bellows(432) is introduced through channel connections (to the left only indicated with a circle) from a pressurized gas bottle through the pressure storage con-

tainer(457). The bolt or inner slide(472) is slanted

30 against the edge projection(459) and stands under the influence of a strong pressure spring, which is surmounted, finally, by the gas store pressure.

Thereby the small bolt is activated by the bowden cable (462) and taken into the slot on the box bottom(448).

Thereby a blind before the nozzle(3) inside the suction cup(1) is also shoved away (c.p.337,Fig.14).

The elastic protective membrane (445) is stretched out over the piston (10) between the hammer sleeve (436) and the thinner. The upper piston (970) takes this in account with slight conical taping. Longitudinal grooves (971),

- 5 Which terminate blind downwards to the nozzle in the piston(10) during the ejection are coincident with corresponding longitudinal(971) and bottom(973) grooves of the injection cylinder, so that the thinner can be expelled by the nozzle.
- 10 The filling up of the chambers takes place, bεlow through the flap valve(11) for the insulins and the thinner, respective water, and through the connective hose(449) for thinner resp. water.
- Below in the middle, the detail of a two-chamber cylinder is reproduced in which the elastic protective membrane is replaced by the folded bellows(445,c.p.Fig.16). The connective hose(449) for thinner is coiled, conducted inside the folded bellows through the piston(970) to the valve flap in the space above the piston(10).
- The variant, below to the left, dispenses with both pistons inside of the injection cylinder(9) and replaces these by a folded bellows, which is compressed in the middle a little by the annular spring(974). The fluids are filled-in on both sides through the connective hose (449) resp. the valve flap into the folded-in in the same states.
- (449) resp. the valve flap into the folded bellows(975).

 During the emptying by pressure from the side of the pressure donator, the spring ring(975) already opens and is held open by the entrance of the acutely locking or opening pin(976), which is centrally inserted on the bot-
- tom of the cylinder(9), so that finally then thinner alone is urged to the nozzle(3) instead of the drug. In a variant, below to the right, the elastic protective membrane is replaced by the folded bellows(455), which extends from the side of the rod of the piston(970) to
- 35 the edge of the cylinder(9), The rod has a thread, in

which the rotation by the nut activates the piston mction. This nut is secured against a lateral shifting and has an outer screw that is driven on.

In all cases, water or other clean fluid can be filled 5 between the wall of the cylinder(9) and the protective membrane or folded bellows, which is not replaced between the single uses.

In the case of an exclusively elastic membrane over the frontal surface of the piston(970), a second sealing membrane is necessary between cylinder and the backside of the piston.

Figure 37 deals with an alternative to the mechanical control gear. Above to the left, the detail of a valve segment is repeated in a horizontal section to a scale about of 2 : 1 (c.p.Fig.19).

Below to the left, a valve is shown as a kind of hose or tube brake, above horizontally, below vertically cut, to demonstrate possibilities of diminishing the

20 streaming of fluid into the injection cylinder, if higher insulin dosages are applied.

To the right in the middle, the detail of an injection cylinder is given in a vertical section (simplified by one injection piston, c.p.Fig.16).

25 Above over the breadth of the page, a horizontal section is shown through the entire gear, below still special aspects.

The power flow runs from the motor axis(53) through the transmission toothed wheels(54) to the toothed wheel

- 30 (643), then to the toothed wheel(642) on the square axis (627). On the latter the toothed wheel(630) is resilient in a bush and shiftable with this and connected with the sliding socket on the square rod(644) by connecting sheets. The square rod directs a wedge against the spring
- 35 tongue on the oinion(8CC, detail below in the middle). Below to the left, the projection of any toothed wheels

up to the drive of a toothed wheel (645) for the metering screw is represented in a frontal section.

Above in the horizontal section, a upwards folding of the axles was executed, to clarify the function. From the four operating toothed wheels (above in the horizontal section) both outers are destined for the drive of the forerunning thinner into the injection cylinder. The derivation from the operation wheel to the

- left was conducted. 10 In connexion with the ratched toothed wheel (702) on the same axis follows the punched disk(446) with the bent slot, in which the cam peg runs for nearly for one rotation urtil it transfers its rotation to the toothed wheel (648) for the operation of the hose brake (detail below 15 to the left) through the translation toothed wheels (54, above to the right). The coupling for the idling between an operation function and the gear is omitted here; it was dealed in Fig.13 (814,815,816). The resilient brake(998) against the operation wheels should be 20 superfluous. The metered forrunning, that is to say the elevation of the connective strap(267), also occurs through the axis of the ratched toothed wheel (702) by the screw(357) in a thread bush, which is fastened onto the injection cylinder (9) over the flexible shaft. 25 The connective strap is here not connected with the piston(10, detail to the right in the middle), but it stops the upwards movement of the piston inside the folded beIlows(445) which is filled with fluid. The combination of the lifting of the piston with the hose throttling or
- squeezing with the corresponding coordination of both functions can be still more favourable. Whilst space is permitted for the piston lifting because of a low drug dosage, the hose valve slowly opens for the thinner stream into the injection cylinder.
- The construction above the third operation wheel terminates in a ratched toothed wheel with postponed punched disk for the valve cycle (c.p.Fig.19,20) during the other

metering screw (c.p.121,122, detail above, Fig.9) can be operated by the adjacent middle (second) operation wheel. The toothed wheel(645) serves with its flexible shaft to the lifting, which occurs proportionally to the metering, of the connective strap(267) by means of the screw(649), the thread bush of which is lifted, pick-a-back, by the screw(357) and which is correspondingly connected with the upper bush of the screw(357), the former being adjustable in the height. The connective strap can be rotated.

The connective strap is rotable around the end of the screw(649) and is formed of a dcuble of the fork piece (650) with a wedge on edge, adapted to the forerunning of the stroke of the pressure dcnator (not shown). The fork pieces are held together by a spring-suspension (here as

tension and pressure springs) above the folded bellows (445) with the effect to imped the latter. The flitting down of the pressure donator urges the fork piece sidewards by the wedges on edge, before it depresses the

folded bellows and therewith the piston(10) for the ejection. (The double point-and-dash lines for the demonstration with arrows refer to the connectedness of the vertical and the horizontal section through the injection cylinder(9) and, that is to say, of the plan view toward the altered region of the connective strap).

The swivelling away of the connective strap can also be achieved through a lateral tow line or a rod, one of both being activated before the pressure donator has toached the folded bellows(445) or its strengthening plate.

The solution in Fig.16 needs the rail guidance of the thread bush or screw sleeve(857) along the cylinder wall inclusive the spring braking as resistance against the pressure of the fluid which streams into the injection cylinder, what weakens the impact of the pressure dona-

35 tor.

The construction of the valve as tube-type brake, below to the left, principally corresponds to that as customary in the trade tor drug infusions or approximately to the hose pumps in the blood transfusion matters and in the laboratories. The hose is led within and out through bores (which lay behind the section plane in the vertical section) in the valve pot, whereby the hose segment is stored at the edge. The hose is gradually narrowed on a radial partial sector and the fluid stream is throttled b∈cause an expansion of the pot wall (in the horizontal section sickle-shaped) through a cross sleeve which is introduced from the turnable lid (here spring biased). The fluid valva, above to the left, is suitably driven as a double pump which is arranged as a store, one over the other, by the same axis. The supply of water or thinner to the injection cylinder can be completely hindered by them. The leaf spring(654) serves to the stabilization of the respective valve position; the leaf spring(887) serves to the transformation of a thrust movement into the sectoral turning by carrying along with it an excentric cam. (If the rotation of a toothed wheel is translated to the rotation center through a flexibel shaft or similar one, the leaf spring can be omitted). The motor rotation is transferred not only from the toothed wheel(643) to the toothed wheel(642) and therewith to the square axis(629) with the pinion(800) for the function of the control gear. The rotation of a toothed wheel which is positioned under the toothed wheel(643) is simultaneously transferred to the toothed wheel(630), which can be shifted along a further square axis and which permanently meshes with the pinior (80C) by the connective or holding plates(124) with the toothed wheel, and which is slided along with the latter as a driving element for the pinion. The representation, above the toothed wheel projection in a frontal section, relates to the carrying with or transport of the pinion(800) by means of an elastic

- 85 -

BNSDOCID: <GB__2307960A__L>

5

10

15

20

25

30

3.5

spring or tongue and is a clapping down for the explication of the conditions around the square rod(644), which are above merely drawn in the total representation with irregularly dotted line. The springy wire bow(655) 5 on its device base ledge is shoved more upwards and erected and supports the stabilization of the position of the toothed wheel(630) meshing with an operation wheel in each case. The springy wire bow exists also quadruple in a staggered arrangement. When the motor is activated, the pinion(800) shifts, for example, to the right on the screw(801). Its spring tongue transports the sliding socket or sleeve on the square rod(644) as long as that meshes with the first operation wheel, a circumstance which is recorded through electrical contacts (not shown) to the electronic control unit. By pole change, its rotation direction is now altered, and the pinion(800) is lifted to the left as far as it corresponds to the programmed operation function through the operation wheel and the joined toothed wheels. The intermediately ratchet toothed wheels ar now able to let through the motor rotations during the shift-

the pinion(800) to the concerning operation wheel after the motor poling is once more changed to the right until the pinion contacts with the respective operation wheel. A further shifting of the pinion to the right leads the tocthed wheel(644) up to the contact with the second operation wheel by the thrust of the sliding socket.

ing of the pinion to the left without function. They

transfer then the operation function during the return of

But the second operation wheel can also be passed over by bringing, of course, the toothed wheel(630) into mesh with the second operation wheel by use of the spring means cross to the motion axis of the toothed wheel(630), but the former being then further immediately shifted to

35 the right (still in the tolerance field of the idling

10

15

of the punched disk). (A short chopped or staccato pcle or direction chance at the motor is suitably to support the clearance from the operation drive during the passage of the operation wheel. When the pinion(800) reaches the toothed wheel (803), the sliding socket before receives resistance with its stroke, and the spring tongue of the pinion crosses the wedge nose of the sliding socket. The toothed wheel (803) is activated in the mesh of its lateral maps(783) with the maps of the pinion, and therewith, through the toothed wheel (793), the control gear up to the screw sleeve(850), the sliding screw(352) for the oprings of the pressure donator. The pinion(800) must be led back under the passage of the toothed wheel (630) through all operations wheels to the. toothed wheel (802) for the return of the sliding screw (332). This is done with the aim, to rotate them together with the screw(801) in the counter direction (to that of the toothed wheel(803)). During this backward motion of the pinion(800) to the left, it is possible to command desage corrections by the control unit according to the above mentioned filtered pendulum method; but also the return of the screw(649, detail of the injection cylinder) is possible. Two ratchet toothed wheels(as 656) can be radially displaced arranged in a counter running working double for the exchange of the drug cartridges. They can be used against a spring back stop for the change of the effective direction through a fork bar (dashed-and-dotted indicated under the screw(801)) on the slide switch(717,c,p.Fig.29).

As the ends of the fork of the drawn or outlined bar indicate, an automatic sliding by the pinion(800) is also discussed. For that, a stationary relisient roller(348) is used on a roof slant(156) which is shoved past under that by a bar.

But two additional operations wheels with opposite working ratchet toothed wheels can be used for this purpose.

1 G

15

20

Because the metering process does not occure simultaneously, the necessity of additional fluid valves arises. It is derivated also from the hitherto described practice to employ the way of the pinion, which is indeed already destinated, for functions, which are fixed relating to the number of rotations or the extent of sliding distances, and from the practice, to use the screw rotations for indetermined functions. The high translation for the sliding screw of the pressure donator but could then have the consequence of an overlenght of the screw or the necessity, to activate, also in this case, the sliding screw only intermittently in strokes by pendulum motions of the pinion and the ratchet toothed wheel.

Figure 38 continues with a detail in the horizontal sec-15 tion in a scale of 4: 1 the task and its solution of Fig. 12. Mainly, where separate drives are used for the metering(c.p.Fig.38,39), for the main drive for the tensioning of the spring of the pressure donator, the problem is given, to arrest sliding movements activated by 20 the bolt. If the wedge slide(274, Fig. 18) is moved by means of the sliding screw(352, Fig. 9, 28) both final extents remain avalaibly for other operation functions after the lifting of the pressure springs. In comparison with it, an addi-25 tional sliding device would require an overcoming latch, if the sliding screw lead pressure springs(261. 262, Fig. 35) in a lock. After the screwing back of the tension device for the pressure springs, remains an eligible extent for a switching function with highly posi-30 tional stability. The fixation of a connective strap (267, Fig. 37, detail of the injection cylinder without the screws(649), against the fluid pressure in the injection cylinder, requires, for example, such a stop. The wheel segment (794) is rotatable together with the 35 eliptical disk segment(667) around the axis(795, which is transferred upwards into the arrow direction). In a radial slot of the wheel segment, the rectangular tube

5

socket with the cross bar(666) is mounted against a pressure spring. The cross bar was inside led past along the stationary bent ledge(665) with undular profile, when the wheel segment is turned on the cam(663) by means of the thrust rod(661) by the sliding screw (not shown) to the left. Therefore, this cross bar is locked about in the middle of this ledge(665). Further pressure from the thrust rod has allowed, that the latter moves over the curved end of the cam(663). Thereby the disk segment (667) was shifted away so far, that it leans from the inside with its larger extent of the ellipse to the cross bar(666) and fixes it on the curved groove of the ledge (665) with the result of a locking of the motion. The release of the stop happens, if the thrust rod(661) overcomes the cams(663,668) and transportes again the cam(668) back to the right. A further cam(669, indicated with a dashed line) can be mounted on the disk segment, against which the thrust rod pushes during its movement back, resp. to the right, and whereby it pulls the projecting edge of the ellipse away from the cross bar. But the lever is fastened on this for the activation of the operation function.

Figure 39 shows in a longitudinal section on a scale of 2:1 a small solenoid(478) with high speed, whereby the motor axis(53) transfers its rotation through the intermediate control or reduction gear(997) to the translation toothed wheels(54).

Figure 40 shows in the longitudinal section on a scale 2:1 a metering mechanism(c.p.121; Fig.9). Two solenoids (554,555) are joined together to the aim of metering screw. The sclenoid anchors or bolts work against small wedged teeth of a gear wheel (shown in a partially rolling-up) with its spherical end. The gear wheel(637) is

5

10

15

rotated by the solenoid to the left(554) over a ratched wheel, said gear wheel driving the metering screw(157; Fig. 33). The action of the solenoid(554) happens respectively, but the rotation effect is increased by the intermediate gear (997). The ratched gear wheels arranged to 5 run in opposite direction effect one with other the rotation of the geasr wheel(637) or at least not hinder one the other. Coarse and fine metering and therewith the total metering can be effected quickly in such a manner. The rotation and the arresting of the wheels shown in a 10 rolling-up are secured by disks with wave profil in which the leaf spring(654) engages respectively with arresting effect as shown to the right on a vertical view of such a disk with spring. The leaf spring suitably touches electric contacts inside of the notches of the disk and 15 thereby reports to the electronic control unit the position of a perhaps connected metering screw and the number of its rotations. To turn back again the metering screw out of the insulin cartridge after the drug is emptied, the angled bar(163) projects from the bolt of the scle-20 noid, the end of which meshes to the wheel (161) with wedged teeth (shown again in a rolling-up), if the latter is approximated to the angled bar over the sliding bar(162) on the cover plate of the housing. The operation gear thereby takes the sliding bar with parallel axles from 25 the mesh with the laterally fixed gear wheel (160) which had driven the metering screw over a shaft with gear wheel. The operation gear wheel(260) is brought into mesh for this with the toothed wheel (637) over the sliding bar (the springing along the axles being not shown), the for-30 mer driving the metering screw over the shaft (not shown) with toothed wheel. This is done correspondingly to the other wedge tooth position in an opposite direction. Figure 41 shows a schematical longitudinal section to demonstrate the possibility of an combination of different 35 working way distances between the strong pressure spring (261) and the trust rod(661) by the localisation of the

rotation axis(660) which destinates the effect of the lever(872). The latter is joined with the spring(261) and the thrust rod(661) with hinges (drawn with circles).

Reporting to the Fig.32 and the Fig.47-54 the following can be understood, whereby the hammer(121) stays for an guiding pin of sensor elements:

In the case the measuring differences are still to high, the alarm(304) is activated.

- The button(306; Fig.) can be pulled then over the towline(305) emerging from the seat valve(134) over the roll (307) on the cover plate, to ventilate the suction cup, in case the commands to the mctor for a tensioning of the tension springs(729; Fig.) was not yet successful.
- After suitable skin condition has been confirmed, the solenoid with the hammer(121) is operated at the functional stage B and thereby the cannula is pricked into the skin and the sensor thread pushed under the skin. The solenoid remains activated for 2 4 seconds resp. for the time for saturation of the sensor thread with tissue liquid,

then the sensor thread is retired.

The current, derivated from the sensor thread, is admitted to an amplifier to the measuring instrument and the measured values signals to the e.c.u.(300). After the measured values are compared with the metering programme, the solenoid(554) and the metering mechanism(125) receive, if need be, impulses for the injection.

The injection amount is counted and controlled on the contacts (654). After the injection is completed, the sclenoid with the hammer (121) is activated again by the e.c.u. (30C) at the stage D and thereby the sleeve (691) is retired and the suction cup ventilated and the retreat of of the sliding sheets (9) by the tension of tension springs (729; Fig.) is initiated with impulse to the mctor.

The device can be used advatageously at night for protection against low sugar levels during sleeping. For this,

25

30

this fastening rings or loops on the housing are provided through which retaining webs are drawn. The device can be fastened now with the suction cup against the skin of arm or leg. The three point contact on the suction cup with the skin activates the measuring function and falling short of a determined measured value causes the alarm to be activated. Because the sleeper is in the habit of turning, the device usually comes out of place always to new skin areas.

10

5

Programming

According to the dosage programming of at least two sorts of insulin, be advised of the suggestions in WC 86/ 15 01728 (Injection device with sensor, PCT/DE 85/00313). One proceeds there, first with the processing customary in medical practice, whereby different insulin sensivity is considered with correcting factors on programming. The advanded computer technique with chips also for spe-20 cial single problems today allow further improvements for patients cooperative. Thanks to the amplifications described in Fig. discern, for the future, between alterations of the basal secretion or the level of the basis rate of insulin 25 (set forth with page 95)

and the individual sensitivity for insulin. Additional to a timed input of planned meals with triangles and of working energy with a stronger combustion of carbon hydrates in rectangles, a one point input is made always by push-button in the centre of the panel or key board belonging to the planned date of the next meal.

The computer compares now the fed planes -triangles for the carbon hydrates ingestion(supply) narrowed at the margins by rectangles for the energy consumation- to the rhombes -relating to the working insulin resorptionwhich are altered by the individual correcting factors, and tries a surface masking first for immediately working insulin. If the chosen date for the next injection lies out of the duration of effect of immediately working insulin, the computer shall attempt a correspondance of the surface with depot insulin, which it supplements with immediately working insulin for the initial hours. If the planned date for the next injection lies in too great a distance from a still sufficient effect of depot insulin, the computer activates the alarm function and indicates an earlier date for injection. In the case that the patient uses the injector earlier as planned, the computer considers the supposed effective rest surface caused by the antecedent injection for the new programming. By effectiveness checkings of the insulin after determined test meals with a step-like increased load with carbon hydrates, an eventual decrease of the insulin effectiveness can be ascertained. It can be placed to account for the existence of an estimable basal secretion. On this base the insulin treatment is essentially improved in the future.

The patient shall alternate timed notices of meals by input with the key(top,c.p.Fig.l5), if he took up other carbon hydrates amounts as planned originally, that is earlier. The computer shall take into consideration these corrections while calculating the next insulin amounts. As well as for the input of planned meals as for their sup-

5

10

15

20

- 25

30

plementary correction -of course also according to the date- the patient can use the auxilary means of a foodstuff table on the underside of the device. Pressure to the respective symbol or picture for quality and quantity (bread or roll, egg, glass of milk a.s.o.) effects the data exposition of bread units (b.u.) on the display -perhaps on a sidewall of the device classsed with a respective number of the key board or panel similar to a grid square of a map, on the condition that the patient, before he compiles his bill of fare, signifies the corresponding period of input with the coordinated key (or top) to the left, with which the computer classes the point coordination. Of course the informations or inputs relating to the planned body stress shall also be corrected past and considered from the computer. The plans as well as the corrections, as arbitrary additional dosages, glucose measuring results, the allowed play and the use of this as planned and administered insulin amounts are made visible on time or topically, preferably on the cargo device in contact with the mains but also in battery operation of the recording device. The characteristic lines -traced=fully executed; dashed=planned; dash-and-dot lined=ccrrected- of the recording facilitates the interpretation of this: Laying or prostrate triangles again for the carbon hydrates feed, prostrate rectangles for power (output) whereby the under ledge of the strip can also be used as centre line. The glucose value of the blood or tissue liquid are suitably printed up in columnes raising from the lower strip margin, the insulin metering in hanging downward columns from the upper recording stripe margin. The recording tool is peferably mounted across the paper stripe or tape transport. Differences between expected (calculated) and measured values can be clarified by hatching. But the calculated insulin resorption surfaces are signified together with their composition of different insulin sorts. (All this is demonstrated on Fiq.56)

BNSDOCID: <GB___2307860A_____

5

10

15

20

25

30

Figure 42 shows a segment of a recording tape of a recording device(80; Fig. 31) with minimal indices belonging to said device which are described on page 89. The standing column with 150 mg% identifies the ascertained tissue glucose level, the hanging columnes with 40E and 80E depot, the administered insulin amounts. The dashed triangle (the half of this one which has, been input into the panel) stands for a carbon hydrate load of 3 bread units, the triangle with dash-and-dot lines marks the, a little later admittedly eaten 5 breath units. Above in the 10 quadrangle, the planned work achievement of 120 Watt is drawn-in, inside of quadrangle and next to it the admittedly from 120 Watt to 90 Watt reduced, and a little shortended and time-shifted achievement. The planned next time (dashed circle) has been postponed until later (lined circle). The glucose level was banked with 210 mg and ccrrespondingly banked insulin amounts have been administered. The calculated deviations of sugar values and insulin metering from the earlier exspected values, and flashed the with signal connected warning with the pro-20 posual to the patient of an advanced later (next) control time (circle with dash-and-dot lines) are shown. The time grid has been omitted.

- 25 Figure 43 shows a tabular calculation of the insulin dosages in consequence of the imput loads with meals and achievements by the patient. A PC was used with the programme QUATTRO PRO 5,0 from Borland for a simplified form and a an atypical case.
- 30 To the left column, a time scale is shown with time date to which 6 hours should be added. The column for the sugar values follows with still underlaying insulin effect of earlier insulin treatment. Alway read from left to right, three programm column succeed with planned meals for 3 bread units(BU), 1 BU. 6 BE and 5 BE for the

1th.,3th.,and 13.th hour (real time 7, 9, 13, 19 o'clock).
One supposes that the effect of immediately working
beginns first after 30 minutes and its working decreases
in 3 hours (whereby the sugar increases in 20mg% per BU).

The 4.th (broad) program column shows the influence of
a work achievement of 50 Watts for 3 hours, which ifluence
ce decreases therethrough in further 2 hours
(16 to 18 o'clock). Just to the right, the column representates the insulin levels, as added with the data
by the computer, which increase again because a
outsized dinner.

Figure 44 takes the over the calculation results of the last column of the table Fig.57. One assumes, that immediately wcrrung insulin depresses the sugar level about 4 mg% per unit inside of an influence period of 2 hours. 15 The values for depot insulin amount to 2 mc% in 12 hours. At the 1th operative column, the computer calculate the the difference to 160 mg% as the upper desirable value, ard then at the 2th column the value accumulation 20 out of the tolerance limit, whereby 180 mg% are defined as the upperst tolerance value and 80 mg% as the lower limit. It results the recommendation for 28 unit an 33 unit of immediately working insulin for 12,30 oʻclock and 18,30 oʻclock. The sugar level column as intermediate value is now ifluenced by the apply of depot 25 insulin, as the subsequent column elucidate. At "ds" (difference sugar) are in each calculation 10 tolerance windows are combined, so that the injection of 35 unit depot insulin at 17 o'clock is recommended, 30 to be sure with a warning because of low sugar level. According to the counting range, 5 tolerance windows were combined for immediately workin insulin.

Figure 45 diagrammes a statistic variance function for the ascertainment of the time points for the injections $-9\,$ 6-

BNSDOCID: <GB___2307860A__L>

2010/10/2015

using a time scale of 2,5 hours for immediately working insulin and a such of 5 hours for depot insulin. (setting forth with next page)

Figure 46 shows a schematical set up of a device for a skin control to the aptitude for a puncture. A circuit leads from the battery (volt) to the light source, the light through a lens to the test area of the skin, and is reflected through a second lens to a photo-diode as receiver. From there a circuit leads to the amplier and voltage meter als measuring device.

Additionally to Fig.29 shall be noted, that the triangles and rectangles, which the patient is adviced to input to a panel, shall serve, mainly, to the clearity. It may be suitable in the reality (because the restricted number of possible keys on the panel) that as well loads with carbon hydrates as thus with work achievement are input by respectively two points in a distance of a zero-line or by numbers. The computer is able to make visible on the display as well the differences of the chosen dimensions by the relating latice reproduction as the input straight lines as Figures, perhaps beside the calculated planes which relate to the decay quote of the insulins. The patient is enabled to make running back the time quantization on the panel. The computer can calculatory dislocate the input triangle base or the exit point of the loading straigt line for carbon hydrates according to the resorbtion delay to a later time line. But actually, the linear functions may be transferred in such being exponential with increased experience and further functions may be comprised into the program processing.

- 97 -

15

20

25

Figure 47 demonstrates in the horizontal or longitudinal section, and in a natural size (in a lateral rolling-up of the functional portions), a device for the injecting of a sensor bristle into a skin fold. To the left, the wedge slide for the retreat of the sensor to a scale 2 : 1 is shown. Above, a special configuration of the sleeve cap is demonstrated, the same below to the right to a scale of 3 : 1. The movement runs from the motor axis(53) through the translating toothed wheels(54) for the reduction of the velocity on the square axis(627), then through the sliding socket(125) and the square bar(644) to the catching follower sheat(126) for the turnable slide(127). The toothed wheel(128) is mounted above the follower sheet on the square bore and meshes permanently with the pinion(800) by means of jutting and connection disks. The pinion is shoved along the screw, has lateral maps, and meshes with the toothed wheel(803), which has, on this place, only the function to rotate the screw in one direction. The rotation is permanently transferred through the toothed wheel (802) to the intermediate gear (129) and from there to the nut(130). The sleeve(691) was still moved against the conical bore in the suction cup(1), and both strong pressure springs (261,262) were tightened against their four support columns(854). The relaxing of the springs is prevented by the bolt (472) which corresponds in construction approximately to those behind stop knob(270). But the sliding ledge (134) is depressed with the sinking of the grooved slide(132) by the fork(133). The sliding ledge is fixed by the stop knob(270) against its tension spring then. This is possible first then, if the tension spring(235) is released and depressed on the end of the bowden cable toward the grooved slide. (The small pressure spring behind the the stop knob stores the stopping moment). The leaf spring(136) is in reality turned about 90 de-

BNSDOCID: <GB___2307960A__L>

5

10

15

20

25

30

grees around the axis of the grooved slide and secures the stability in the height of the latter. The bowden line(135) between the grooved slide(132) and the wedge slide(137), again with power storing in a spring, effects the lowering of the latter. (To the left, the lat-5 eral view of the slide frame elucidates the function of the thrust effect toward the collar(139) during its depression). The bowden cable(140) lifts the elastic piston(91), which bears the sensor bristle and has an exca-10 vation for a spherical end of that cable. This happens through the central bore in the screw bolt(352) whilst the folded bellows with high elastic septa between the fold depressions -into which the sensor bristle is stored- is compressed.

The enlarged detail above to the left shows, that the sensor bristle is surrounded by the rubber hose end(92), which itself is surrounded from the sleeve(691) after an air gap. The sleeve cap(111) projects with inner projections through slots in the sleeve(691) toward the rubber hose end and tolerates a certain pressure, exerted from the sleeve sufficiently to narrow the channel of the rubber hose end around the sensor bristle with the purpose, of pushing the latter with high speed through the skin, which is drawn up into the suction cup(1).

The detail below to the right shows the rubber hase end 25 (92) directly laying onto the sleeve(691). The sleeve cap is downward enlarged and has inside maps which correspond to such outside maps on the sleeve(991). The projections which reach through slots below in the sleeve(691) to the rubber hose end(92) can be fitted above with ton-30 gues to cover the slots against slipping out rubber. The annular sleeve(577) goes in a thrust-torsion-device which effects an axis rotation about of 90 degrees with the turnable slide(127) after each lowering, and which respectively orings the projecting tongues(93) in contact 35 either with the grooved slide(132) or with both grooved slides(94,95) for the release of both strong pressure springs through the bowden lines(96), of which only one

is shown(c.p.Fig.48) The thrust-torsion mechanism is more described in Fig. 3. The sleeve(691) is put into the groove(151) by hand and is drawn away again after consumption. But the invention aims, of course, toward the fitting of automatic sleeve or grip change analogously described in Fig.9 to 36 of the European Patent Application No.0 301 165 (published on Febr.2th.89), though for the vertical grip or shell storing.

Figure 48 gives a cross or vertical section through the de-10 vice according to Fig.47 in the level above, of both bolts (472) and in a natural size. Below the detail of the bearing of the strong pressure springs(261,262) is shown on the support columns(472).

The housing wall(16) is there drawn-in and the space for the battery(255) and the electronic control unit(80) is nominated. Between the stop knob(270) and the tension spring(235) the release for the sliding ledge(134) is positioned with the tension spring for the rapid retreat of the sensor bristle out of the skin.

20 For this the fork(133) embraces the bowden line(138) and is dislocated by the grooved slide(132). The latter is shifted, as well as also the grooved slides(94,95) in another switching position, by means of one of the opposite tangues(93) in both directions, whilst it is taken by

the tongue insertions between the follower sheet(126, Fig. 1) and the toothed wheel, and whilst the power is transferred from the electric motor(478) to the pinion (800) with the shifting of the latter along the screw(801, Fig. 1). When the toothed wheels(802,803) are reached, the

30 nut(130) is activated on the sliding screw(352) through the intermediate gear(129) by the pinion at the time in opposite direction. The functional operation between left (=below) and right hand (=above) is:

tightening of the springs(261,262) ----->
/<----release of the springs(261,262)
relaxation of the springs(261,262)---->(switch.over of torsion)
/<----thrust of the sensor bristle
/----> retreat of the sensor bristl.+shell(69)+torsion

S. 141.75

Figure 49 shows in a longitudinal section to a scale of 2 : 1 the sleeve(571) of the thrust-torsion-device with the hammer(121) for the explication of the switching over between the particular functional stages A - D. The sleeve(571) shows the inside of the zig-zag groove in 5 which a small cross peg of the prolongated sclenoid anchor 5 or bolt engages and effects a quarter-turn of the sleeve with each stroke, as far as the solenoid bolt is secured against rotation. The rotation is transferred over the coiled spring(141) and the flank with spherical seat(142) 10 of the hammer to the latter. The hammer shaft is rectangular to the right (that is: distal) and is prevented from rotation in the fixedly mounted bush(143). In the demonstrated O-position of the solenoid bolt, there is a 15 circular cross section or radius inside of the bush(143) so that the torsion effect can operate. (Of course, without coiled spring, if the connection between solenoid bolt and flank with spherical seat is respectively elastic). The hammer area in both detail images below shows a mechanical stop sleeve(144) which as a half groove stops, 20 in each case, the rotation over a respective operating member (A - D). For this there is an angled piece with a passage for the stop sleeve(144) and for the horse-shoelike bent around pin(146) with terminal disk for the biased pressure spring. 25 The lower image shows, as the cam(147) of the hammer has lifted the sleeve(144) against its spring, that the axle rotation is released by the coiled spring(141) yet tensioned over the sleeve(571) and eventually held in a permanent pretension). The cam of the hammer meets re-30 sistance then on the next positioned sleeve(as 144) because the latter lightly springs back against the hammer rotation. Thus the stop mechanism can be found radially distributed. Below, to the left a cross section in the level of the four sleeves(144). The stop of the 35 hammer end for the operating stroke is demonstrated with the four switching stages A - D.

Figure 50 schematically shows in a longitudinal section a device for the sucking on of tissue liquid and an eventual injectior of drug fluid through a capillary(106). This is much enlarged with its sleeve(691). (Mainly, the latter is additionally shortened). The crosses inside 5 the wall of the sleeve symbolize the measuring layer with chemicals which react with substance (as glucose) in the tissue liquid. The capillary is punched to facilitate the afflux of liquid from the subcutaneous space (not drawn), if the upper syringe piston is pulled. The 10 valve slide(107) is just open. When the measurement is performed (over wires to the measuring instrument, nct shown), the valve slide must be pushed (fine hatching) and then the piston of the syringe, which is filled with drug. The supply tube from the valve to the orifice 15 of the sleeve is drawn with dashed lines.

Figure 51 shows the variant of the sleeve for the sensor bristle relating to a device of Fig.47 and others in a scale of 4:1 in the longitudinal section and a breaking off mechanism for the sensor bristle reaching from the right up to the left lower half. To the left, a sleeve is shown, shortened in the length, during the sensor thrust and quite above to the left, a cross section of the sleeve.

The sleeve(691) consists of any tongles(152), which are interraupted by longitudinal gaps, of which only three are demonstrated. A row of props projects from each tongue, which centrally enclose the sensor bristle. The entire sleeve is covered with a high elastic membrane against pollution, which membrane is not shown.

The piston(91) which is shoved foreward into the sleeve, conically rises above outwards and it spreads the tongues (135) asunder whilst the sensor bristle is pushed fore-

35 wards. The wedge slides(137) behind the collar(139) of the sleeve are spread like a vice in a hinge(not shown).

The proceeding shoot-in of the sensor thread (or bristle) is activated according to a mechanism as in Fig.1 ,2 . The rubber hose end(92), which accepts the pressure from the collar of the sleeve(691), is supported against the support(153). The support ring again can be rotated and is connected with the frontal slides for the production of skin folds (respective the suction cup) by means of the props(154), which are indicated there only weakly as analogously described at the cup in relation to the nut (131,130;Fig.47).

The pressure which is stored on the hose end, first narrowes the channel around the sensor bristle. The electric tracting solenoid(555) is operated by the electronic control unit through a contact (not shown) perhaps in front of the strong pressure spring(261). This is done through the lever(159), the curved wedge slide(155), which activates a counter-clockwise sector rotation of the support ring(153), so that the projections(157) come to be situated over the gaps(158) of the support ring and can pass through. The passage of the projections can be facilitated by relating slants in the vertical direction. (Below to the right, the plan view is shown from below to the bearing disk on the supporting ring). The sleeve is now pressed against the sleeve cap(111), and the sensor bristle is shot through the skin. Before the removal of a sleeve, the solenoid(555) must be activated for traction. The props (120), which project from the skin fold shiver (or the suction cup), and are shown perhaps too weakly, let the support ring(158) roll up behind them. The staying between the support ring and teh props(120) is not shown. Inside of the rubber hase end(82), the conducting layers are indicated white dashed lines which continue in the wires(84) on both sides and contact there with leaf springs for a transmission toward the measuring instrument. On the case of the method of the abduction of tissue liquid by a kind of wick, sensor layers would correspond to the white dashed lines, perhaps for the reaction with the glucose of the tissue liquid.

- 103 -

5

10

1.5

20

25

30

Figure 52 shows the variant of the introduction of a sensor bristle according to a bore in natural size in the longitudinal or horizontal section. Above to the right, the construction of the sleeve for the transport of the sensor bristle drawn out in a scale of 2 : 1 . Below the preferred variant of simplificated sleeve.

The demonstrated stage is that of a sensor bristle which is drilled under the skin in a suction cup(1). The electrical motor(478) with the translating toothed wheels(54)

- 10 stands firmly in the housing bottom (omitted) for that; the square axis for the driving wheel (233) is slidable through the latter and connected with one of both carriages, which itself again run along the (dashed drawn) rails The power closing runs from the driving wheel(233), which
- rotates freely, to the elongated toothed wheel or the screw bolt(352). The latter can be moved away from the suction cup by rotation inside of the prolongated nut(130) and takes with it the sleeve(651) in a squeezing seat of its collar(238) by means of the squeezing sleeve(238).
- The rubber hose end(92) around the sensor bristle is compressed, first, through cross projections by the sleeve (691). The inner sleeve(97) around the rubber hase end is supported against balls against the sleeve cap(111) and turns with it, whereby the screwed end of the sensor
- bristle pierces the skin.

 For the largest extent under the skin, the sensor bristle is moved through the screw bar(235), which happens inside of an inner thread of a large toothed wheel which is fix-
- ed between the nut(130) and the transverse spar(251), whereby the screw bar(235) is moved through this transverse spar with its end. The related small drive wheel(234)is driven by a second motor (not shown) or through a control gear from the motor(478). The rapid retreat of the sensor
- bristle takes place by influence of both pressure springs (237) between the projecting ledges on the suction cup and

on the carriage(236) each, which are twice moved upon a rail. This occurs after the bolts(472;c.p.Fig.48,there is only one shown) is released by a sclenoid. (The latter is also not shown as also the vacuum source is omitted).

- The variant of the frontal end of the sleeve(691) shows the sleeve cap(111) firmly integrated around the suction cup orifice for the sensor bristle and this, indeed, with a ball bearing for the inner sleeve(97) which absorbes the pressure of the rubber hose end. The rubber hose
- 10 erd rests on the sleeve(691) with a sudden calibre change, and rotates with the inner sleeve.
 - Above to the right, the detail is shown of a preferred solution between sensor sleeve and suction cup in the scale combination of 2:1. The rubber hose end(92) is firm-
- 15 ly fastened with its one end in and on the sleeve(691). The latter has a fine thread on its end, which works against that one of the nut(130), whereby both threads are adjusted one against the other with regard to their gradient.
- An inner thread of the inner sleeve(111), which is a portion of the device, correlates to the outer thread of the screw bolt(352). The inner sleeve(250) is tightened on the socket(117), which projects from the suction cup. A sealing ring lies also between the inner sleeve and the
- sleeve(691). The rubber hose end is compressed during the rotation of the sliding screw(352) and likewise rotates the inner sleeve(250) with the ccrrugated end of the front side. The inner sleeve is thereby removed from the suction cup and thus an extent as the sleeve(691) approaches
- 30 the former. In use of the device, the sensor (thread) is shoved out a certain distance of the inner sleeve by the screw bar(235) (The problems of the safety covering before use are omitted: they can be sclved by the drawing off of a cap or by an glowing wire loop). The skin (with dash-

ed-and-dottered line), which already clings to the top of the sensor thread or bristle in the punched disk(254, Fig.7) is able to evade to the free thread end first. The thread end is then thrilled through the skin by the rotation with the screw nut(130).

Figure 53 shows the variant of a device for the shooting-in of a sensor bristle under the skin by means of a pressure gas thrust, and this is done in a horizontal or longitudi10 nel section to the scale of 3: 1. Singular images of the stacking sheets are shown above (as detail) in a vertical cross section, the sensor bristle is beared on those sheets for a time. The device can be suitably operated from a CO₂ pressure gas capsule and can make use of additional devices, as such are described perhaps in Fig. 36, but also already in the European Pat.Appl.Nr. 0 2210 OE(Fig.13,17,19 etc.), mainly in that from Mc Kinnon which was cited above.

A gas thrust is conveyed out from the pressure gas hose (893) into the channel of the sleeve(691) through the tube into the channel of the sleeve(691). The pressure beam advances the end plate(214, very exaggerated on the sensor bristle and the latter before itself, wherby the final plate is not able to pass the narrowness(215) on the sleeve end.

The clamp(253) which is conically shoved between the collar(139) of the sleeve and likewise a tube, serves for a gas tightly coupling the conical tube end with the funnel of the sleeve(691). The retreat of the sensor bristle follows from the tension effect at the sclenoid(555) which takes place over the lever(159) to a ledge on the carriage(256). The latter is moved along the rail (252) and in the same. (The way is drawn shortened). Whilst thereby the wedge ledges(99) are drawn back by the carriage, the sheets are approached against their spring

- 106-

bows(85, above in a vertical view) during a pushing off on the bars(355) such a distance, that the sensor bristle is embraced in the narrowned channel between the stacking sheets(86) which are alternatively stringed from above and from below. Thereby a current derivation occurs from the surface of the sensor bristle. Through the electrical (integrated) lines (84), the sheets transfer the current by contact of the conducting rings one with other to the measuring instrument. Each of the lines thereby re-10 sponds to a contact on one sensor bristle side. The stacked sheet, which is shown to the left, with its slots(98) for the wedged bars(99) demonstrates the singular shape (for the spreading of both rows of the stacking sheets). To the right, representations follow of two adja-15 cent sheets in the stage of the wedge bar retreat and after the introduction of these into the slots(98). The solenoid(555) is switched off again after the metabolism measurement, and the carriage(252) returns in the shown position under the working of the pressure spring 20 (237). The wedge bars thereby spread again the stacking sheets, so that the sleeve can shoved over the sensor bristle. (Mainly if the suction is introduced from the jet pump through the pressure gas hose(893). A repetition of the sleeve retreat permits its removal for a replacement of an unused one. The chamber (354) arises between the cone for the uptake of the sleeve in the section cup(1) and the punched disk(254). this chamber is plate-like downwards, and closed by the suction cup edge. One demonstrates the slightly cambering of the skin against the sensor bristle through the opening of the punched plate or disk. The light beam(353) can be reflected on this small skin bubble and projected along (or through) to the related sensor before the shoot-in of the sensor bristle. The optical skin control is essentialy facilitated in this manner because surface irregularities can also be better detected. (A hair bulb follicle cculd perhaps not pass the small opening of the punched plate or disk).

25

30

Figure 54 shows a natural size in a horizontal or longitudinal section, a device for measuring purposes in which the sensor bristle is shortened to a small double or sensor cylinder(216), the bottom surface of which has measuring layers each of different sensibility reach for glucose. The carrier thread (of any given material, if it is solved from the sensor layer for the measurement) with the sensor cylinder -which is here stacking in the skin- is drawn very overdimensionally because it has in reality a diameter about of 0,3 mm). Quite to the right in a scale 4: 1, the carrier thread, that is to say the carrier capillary (217), is shown inside of a measuring guiver. The latter consists of a stationary basic cylinder(219) and the cap cylinder(218) which is shoved onto the former, both armed with laser sources as photoemitter(580) and photosensor(581, or eventually with use of light conducting fibres with auxiliary lenses and postponent ccupling toward the sensor as schematically drawn above. The electrical wires (6, each doubled) run to the measuring device (not shown). The shoot-in device relates perhaps to that which is described in Fig.6, whereby the sleeve(691) for the bearing of the carrier capillary or the carrier thread is shortened. The sleeve(691) is connected with its collar(139) with the collar of the pressure tube, into which leads the pressure gas hose (893), by means of the clamp(253). After the sensor cylinder is saturated with tissue fluid, the bolt (472, Fig. 1, 2) is retreated and the tension spring moves the sleeve(691) back by means of the carriage(236) on the rails 30 (252), so that the sensor cylinder leaves the skin and the suction cup is reventilated. (The suction sources are again omitted because it is known and anyone used). The sudden calibre change between the small sensor cylinder and carrier prevents the passing through of the 35 skin; the frame of the cylinder in the end of the carrier serves for the security against a break off of the cylin-

der.

10

15

Below to the left, the dome-like end of a diagnostik pen with a large carrier with a final small sensor cylinder, which can be shot in the skin, after the pen is pressed against a skin part over resilient soft tissue, so that the fixation of the pen top occurs in a trough of skin.

The sensor cylinder can be shot into the skin by gas pressure or spring and the broad carrier works as a kind of drawing-pin. The measuring evaluation can be performed in a device as shown in Fig.7 to the right. The central beam(108) leads as a laser beam (dottered-dashed drawn) through the central channel(dashed).

Figure 55 shows below, to the left, the device for an urine sampling and a metabolism check-up to a scale about of 1:5 . To the right thereof, the detail of the lower portion is given to a scale of 1 : 1 . Just above, the sampling device an over view is given to a scale of 1:3, below two stages of the sampling operation in a detail around the test strip. The tennis-racket like holding frame(606) -perhaps for woman- can be sticked through under the toilet seat and can be held by the grip(611). The grip has lateral insertions to be folded down before use. Inside of the frame a paper sac(616) is attached with a free upper portion which canbe constricted and thereby closed by a lace (608). A test strip(614) is inserted through a slot into the bottom of the sac so that the measuring reactive layer is able to contact with urin. On the free end of the test strip outside the sac, a string is fastened and fixed by an adhesive plaster(609) which tightenes the slot. On the end of the plaster, the string(610) is bent in the counterdirection first, and leads then in a loop(613) which can be hanged or the hook of the spring balance before the filling of the sac by

of the spring balance before the filling of the sac by urinating. The loop of the lace(608) can be fastened on the hook of the spring balance before for the ascetain-

5

10

15

20

25

30

ing the urine weight, which is recorded to the computer, in particular if the tube(602, below to the left) is attached to the injection device perhaps by clamps(not shown). After the alarm which indicates the running up of the reaction period, the sac is held over the toilet, the plaster is is rolled and pulled away by tension from the string. The slot(612) is such a way opened, so that the sac can be emptied. (Second stage as shown under the first one). The test strip can be evaluated by the photometer of the injector after it is stuck in a special measuring casing(not shown).

The complet view demonstrates the spring(601) of the tension balance with the sac(616) on the hook.inside of the tube(602).

The detail gives a longitudinal section through the central pin(617, interrupted and shortened), the hollow piston(603) which slides along the central pin and is fastende with the spring(603), while the central pin is stationary above on the tube(602). The sliding spring (618) renders the weight measurement possibly by using a kind of Whitestone bridge.

Figure 56 shows a low sugar warning device for the use at night. This is done below in a longitudinal section, above through a detail of the measuring drum in a cross 25 section. The ball(619) is fastened in the center of the drum(621) by an elastic wire. Four contacts(622) are distributed around the circumference of the drum, which is mounted in the housing(16). (The latter is buckled on an arm or leg or an other body portion by the belts(623). 30 With each touching of the ball with one of the four contacts(622) on the drum, a current circuitry is closed to the condensator(625) which is laden over wires (dashed lines) from the batteries(255). An alarm(628) is activated from the control unit(80), if the condensator load 35

1 G

inside of a destinated period exceeds a regulated measure.

The influence of an increased perspiration causes the current amplify between two pales (+/-) on a special pad 5(629) of fabric which can be taken under consideration and regulated for the alarm by the user. (Wires or leads are dashed sketched, the plaster is clapped foreward from the underside of the housing in reality facing the skin. The injector (with its diagnostic device) might be acti-10 vated through the leads (631) instead of the alarm.

The invention shall not be narrowed to the given examples, but the claim for protection should be expand to similar solutions, mainly to combinations but with 15 prior mentioned inventive elements. In this manner, a single slide can be moved against another which remains fixed on the housing. A linear piston-cylinder pump can be used for the suction production, instead of the mounting of a rotary pump (as such from Wankel 20 type) The skin fold can be raised also by adhesive means as shown in Fig.1 of DE P 37 08 031.8. The operating functions may be distributed in any manner between motors and sulenoids. The torsion-push-sleeve can be multiply its functional stages from four to five or to 25 any mcre, if needed, as in the example of Fig.55. A multi-functional solenoid could permit the change between single an permanent functions as described in Fig. 9-14 of DE P 37 08 031.8. The examples could be set forth and should be comprised all inside of the claims, which are in 30 the following are set out:

The following pages are an insertion on *) page 113:

The supply of fluid, especially said of thinner and water for a jet injector, was to keep slightly accordingly to a main task of the invention for a pecket portable injector. For that reason, it is to proposed to provide the injector in each case of apply with a maximum daily desage of such space needing fluids and to store those in an auxiliary or servicedevice by providing it with a multitude of daily single desages. That service device is preferably at the same time the charging device for the batteries of the injector and may also comprise computer capacities and a recording device.

Diminished supply cylinders according to Fig. 7 could be used, but the coupling on would be more expensive. That is why it is provided to filling thinner as well as water on the same side toward the injector, of ccurse. The containers, perhaps follded bellows, can be thereby arranged one above the other but also one besides the other. They are suitably again combined to a unit. The connexion to a chain which runs around in the supply device facilitates the supplying. For that reason, both respective supply containers can be embraced by a kind of frame plate on the end which is turned away form the exit socket. They can also be connected with an adhesive tape on the side of the exit or filling sockets, perhaps along to these, and they can be shoved on this way into the cylinders of the supply device, which cylinders are used again and again. (The adhesive tape is drawn off later in this case). The exit socket or exit sockets are suitably introdurced into a chamber on the side of the injector, which chamber can be heated by electrical wires for the aim of sterilization. The transport of the container out of the chain in the service device into the injector and back again can take place by pressurized air. The latter may be derivated from the bag under the cover sheet(c.p.Fig.21) of the injector while it is depressed. (Such a solution postulates an addition valve position in the injector). But also a blow-

er can be installed in the service device or (and) a boiler for the heating of the used air or a capsule with pressurized gas with the related valve means. From the side of the service device, a (wedged) slide can also be presse the repective container unit against a pressure in the injector shaft. A premature expulsion of the container unit out of the cylinder is prevented by a sliding lid, which is opened, for example, against the springing means, when the injector is shoved to the service device inside of a rail guidance. (A safety interlock is suitably here against an inadvertently operation of the sliding lid. This safety interlock may be mechanically or electro-mechanically). The container unit can be lifted into the injector also by means of a telescopic threaded screw or sleeve, similar as one on a jack for cars. The transport of the container chain results, for example, through a driving latch. The latter can pass, first, a container unit while the injector is shoved to the service device, the former being locked then against a restoring spring. The stop of the sliding carriage for the driving latch is released by a solenoid or motor tension first, when the used container unit is led back to its ealier seat on the chain. Thereby a new container unit becomes situated under the injector shaft an can be transported into them. The motion of the chain is braked by at least one spring biased roller, for example, which serves at the same time for a chain tensioner, if such a chain must be replaced in totallity. A counter carriage with ratched or driving latch can be provided for the balancing of the drive. This mechanism is tensioned during the notion for the separation of the injector from the service device, but the driving latch of which is released together with the other one. The developping motion moment is counter acting related to the device, but synergistic related to the container chain. The two, four or more sprocket wheels could also be driven by a motor.

Because the injector should be preferably shaped flatly, it is recommanded to fitting the rail guidance between the the injector and the service device in such a manner, that the container can be inserted into the injector in a laying condition, what means parallelly to the axis of the injector. The injector can be therefor clapped about 90 angle degrees and edgeway shoved to the service device. Of course, the coupling can be also performed side to side with a rectangularly clapping or turning of the chain axles in the service device or the container units are rotated around its bottom surfaces, which are beared on the chain, or they are starlike fitted in a wheel. Finally, a filling up again of small permanent containers for thinner and water in the injector may occur from large containers of the service device, if precautions are made for an airless and sterile coupling, as analogously dealed in DF P 25 51 991.9, P 25 51 992,0, P 25 51 993.1 and WO 86/o1728 (PCT/DE85/00313).

Figur 57 shows in a horizontal or longitudinal section a sevice device for an injector with a section line under the replaceable cover plate(283,Fig.6C below). on an about natural size. To the right, a horizontal section of a variant of a container unit is given inside of a package cylinder to a scale of 2:1. The rails(519,c.p.Fig.60 below) of the service device serve to the fastening of the housing(16,c.p.Fif.60 above) of the injector. The package cylinders (395) can also be permanently used portions of the device here. They are connected by a tape to a chain one with the other. The latter is led over the four sprockets(714) between both pressure coulisse ledges(250) and is braked by the rollers (521) on a leaf spring. At least one of the latters can be beind back against its leaf spring and allows a prolongation of the chain, so as its changing is rendered possible. the driving latch(522) turns against the pressure spring on the carriage(523), whereby its motion is terminated by a locking pin (black). The carriage runs on a rail

(dashed lined) with its cross plate(530) against the pressure spring(524). The cross plate passes the soft slant of the stop(525) during its sliding by the projecting lid ledge(526, Fig. 60 above) and it is locked behind the steep flank or edge. The driving latch has thereby passed the next package cylinder while it was turned about its axle against the reset spring. When the stop(525) is retired in the surrounding shaft against a restoring spring(not shown), the movement of the carriage is released and the driving latch shiftes one package cylinder to the left. The enlarged variant, to the right, shows containers for thinner(90) and water(190) inside of the lower portions (382) surrounded from the upper portions(527) of the injector shaft (c.p.Fig.61). The exit sockets(528) for the fluids are centrally positioned. The socket(529) on the connecting sheet of the container unit builds the connecting axis to the adjacent (left) container unit, from which the right one lies below in the bore. Pins (not shown) of the transport chain of the service device, project through the sockets. Each container unit can be lifted along the pins into the injector shaft.

Figure 58 shows to a scale 2: 1 a vertical or cross section through the upper portion fo the container unit of Fig.57(to the right) with a portion of the receiving injector shaft.

The exit sockets(528) are shifted into the bores of the uptake cover(532) of said shaft and are sealed by two sealing rings against it. The upper space which is tightered by said seal rings form a chamber which can be heated by the incandescent wire(4) which is feed by battery(not shown) through the leads(6).

Figure 59 shows in a longitudinal section to a scale about of 3: 1 a variant of a container unit.

The exit tube(533) leads from the folded bellows as container for water(190) upwards and is sealed against

inner lip of the uptake cylinder(534) of the injector. The terminal ring(535) is shoved into a recess of said uptake cylinder with a further sealing ring and expells the thinner of the container(9C) through the opening(536) to a hose(not shown). The tube(533) can rise inside the inner bore of the uptake cylinder during the emptying of the water container. The thinner exit occurs above in a hose.

Figure 60 shows, above, a plan view from below to an injector. The sliding lid(537) is shown in its rail guidance (dahed lined) with its projecting ledge, on which the lid is is shoved and opened against a pressure spring by the lid ledge(526) of the service device. Before, the end of said lid ledge(526), running in a slot of the injector cover sheet, pushes the springing lever(539) out of its zig-zag profile on the sliding lid.

Bove a schematic cross section is given, showing the rail guidance for the connection between service device and injector.

Figure 61 shows in a longitudinal section a container unit according to Fig.59 in an injector shaft. Only the pressure spring for the leading back of the unit is shown an the stop for the downwards working sleeve of the injector shaft. Above the telescopic threaded screw for lifting the container unit into the injector from the sevice device.

Figure 62 shows a row of container units in the service unit, unused and used one. A rubber ()bow allows a tightened fixing of one unit under the injector shaft. The transport takes place by presserized gas through a channel in the rubber bolter an sideward through hose(387) in the uptake cylinder of the injector with the relating fluid derivations.

Figure 63 shows a filling device for fluid from a large supply containers in the service device to relating small

containers of the injector. The large folded belows has an exit tube which openes in a non-return valve()inside. The surrounding cylinder of the small folded bellows ends in a screwed on case with another non-return valve(). Both non-return valves are opended, after the large folded bellows is showed to the right by the angle piece() of the service device. The oping is performed by a central pin inside of the exist tube of the large folded bellows. Between the uptake cylinder() of the small folded bellows and the exit tube() are two sealing rings fitted and a heating device() for sterility.

Claims_

1. A system for diagnosis and therapy of a living being on condition of metabolism alterations c c n s i s t i n g of at least one housing with injecting means for drugs through a nczzle through the skin of said living being with at least one container for said drug and at least one injection cylinder with pressure donator for an expulsion of said drug and matter for the cleansing of the injection channel, by an expulsion of a portion of said matter following the drug injection with the same injection beam, which matter, if fluid, is also used for a 10 body friendly thinning fluid for the drug, means for the production of a skin fold to guarantee space for the drug under the skin, cleansing means for said nozzle to prevent a pollution of 15 the drug, metering means for said drug and for said cleansing means, means of a mechanical and electronic programme control including the control of dosage with power source and a kind of programme panel with switches, and 20 preferably means for an optical skin control for the adaption for the puncture, and preferably means for the metabolism control, interacting with said electronic programme control.

25 2. A device according to claim 1 , wherein said injection cylinder contains an intermediate pistor to separate the drug from a fluid serving as said cleansing matter and sd thinning fluid, and including supply leads for the filling of the chamber between said intermediate piston and the nozzle with drug and even-

tually with thinning fluid and the space behind the intermediate piston with thinning fluid, and containing valve means working on the intermediate piston which opens,

3. A device according to claim 1, after the drug injection. wherein drug and cleansing or thinning fluid are metered filled into two separated injection cylinders and expelled one after the other under the control of the mechanical or electronic programme control.

- 4. A device according to claim 1, wherein said injection cylinder is a thin tube which is filled before the apply of pressure by the pressure donator without an intermediate piston with drug and cleansing and thinning fluid before the injection.
- 5. A device according to claim 1,
 wherein water or other cleansing fluid is stored in a
 container as means for cleansing the nozzle and a
 tube connection lead to each injection cylinder

 and a filling up cycle is provided by the programme control
 with an ejection through the nozzle between each
 drug injection operation.
- 6. A device according to claim 1,
 wherein a kind of blind or lid is provided before the nczzle with mechanical means as a portion of said mechanical programme control to push away said blind or lid, at least one of perhaps two, before an ejection or injection procedure.
- 7. A device according to claim 1,
 wherein water and the cleansing or thinner fluid are
 combined to a single package unit, whereby the
 valve inlets are provided, which are protected by
 protective foils before the installation into the device,
 on the opposite ands of said package unit to performe
 the coupling with the supply hoses during the closing
 up of the package unit inside of the device.

30

1.5

- 8. A system for diagnosis and therapy of a living being on condition of metabolism alterations c c n s i s t i n g of a housing with a portion adapted to be set on the skin of a living being and means to receive sensor means
- in a sterile condition and pushes said sensor means through the skin without of an introduction of a cannula surrounding that sensor means, and to retract and to bring into contact with chemical substances for a metabolism measurement, and comprising
- a mechanical and eventually electronic programme control and power source, consisting further of signal producing and transferring means for a measuring device, which transmits the measured signals to a display and a recording device and over means
- of programme control, which can also be positioned outside of said housing, preferably to an injector with nozzle and atleast one pressure donator.
- 9. A devise according to claim 1 and 8,

 20 wherein a elastic hose end serves to support a sensor tread or bristle, which is able to take up tissue fluid under the skin, and is temporar y compressed to guarantee a conduction of the just mentioned sensor means against the skin and said hose end preferably fitted inside with electrically conductive layers temporary in contact with wires toward the measuring device and said conductive layers then in contact with adjacent chemical substances which react with aminteresting metabolic substance.
- 30 10. A device according to claims 1 and 8, wherein a sensor thread or bristle as sensor means are temporary embraced by stacking sheets in a row with current conducting portions in contact with the wires toward the measuring device while the sensor means are situated outside of its protective sleeve or a hose end.

- Il. A device according to the claims 1 and 8, wherein a cylinder with chemicals, which alter their colour by influence of an interesting metabolism substance, is put into the end of a carrier thread, preferably inserted and fixed a short distance in a bore of said carrier thread.
- 12. A device according to the claims 1 and 8 ,wherein a sensor thread or bristle as sensor means isinjected through the skin by a pressurized gas stroke.
- 13. A device according to the claims 1 and 8, wherein the puncture of the skin is performed in a suction cup as means for the production of a skin fold, near the suction cup edge in a direction which deviate from the the suction cup axis.
- 14. A device according to the claims 1 and 8, wherein a single cartridge is used for the expulsion of drug with a special own nozzle, which is inserted into said cartridge.
- 15. A device according to the claims 1 and 8, wherein suction as means for the production of a skin fold develops by the enlargement of a bag, which is stretched between a fixed housing sheet and a movable lid and widespread fastened on the m and operated by pressure springs between the housing and the lid, which are tensioned by manual pressure and temporary fixed inside of an locking device.
 - 16. A device according to the claims 1 and 8, wherein as means for an optical skin control a kind blind or visor with a hole is proviced near the base of the skin fold, whereby the skin can be approached to the sensor means before its use nearer as the adjacent skin, which leans on the blind, and which hole marks

35

the puncture area, and whereby light is tangentially projected through the small bubble in said hole against a photo receiver in connection with a measuring device and the electronic programme control.

17. A device according to the claims 1 and 8, wherein as means for an optical skin control a kind of window on the edge of a suction cup, as means for the production of a skin fold, has a window wich projects light against the skin and reflects it against a photo receiver, preferably connected with said means for the programme control, which checks the condition of the skin in the puncture area by calculation.

- 18. A device according to the claims 1 and 8, wherein a control pan el exists on which a diabetic inputs the planned time points of meals with the planned contents of and load with carbohydrate as well as the period and heighth of planned bedily work capacity and might correct later correct the mentioned inputs according to the reality, whereby a computer as means of programme control compares the inputs belonging to the life style with programmed data relating to the individual sensitivity for insulin sorts, preferably with different working profile, and calculates the optimum dosage and further advice.
- 19. A device according to claim 1, wherein a kind of spectacles for diagnosis are provided with motor driven adjusting wheels which adjust photo emitters and photo receiver tangentially to the cornea for a laser measuring of atleast one metabolic substance.
- 20. A system for diagnosis and therapy of a living being on condition of metabolic alterations c o n s i s t i n g of a sac, preferably with a tennis-racket formed frame, which can be used over the toilet, and a lace which can be

fastened on a balance, further a test strip projecting with its metabolic measuring layer into the sac, and with an end which can be pulled away from the sac for the evaluation of the test strip.

space

- 21. A device according to claim 1, wherein a service device, perferably serving for a battery charging at the same time, contains at least one larger supply container with fluid and means are provided to fill small amounts sufficiently for the need of one day at least, into at least one smaller container in an injector.
- 22. A device according to the claims 1 and 21, wherein the supply in the service device is divided in a multitude of single containers, preferably rowed in a chain and exchanged into an injector one after the other.
- 23. A device according to the claims 1 and 21, wherein a water and a thinner container are joined to one unit with fluid exit in one direction.
- 24. A device according to claim 1 and 21, wherein at least one container of the service device and at least one container of the injector, the latter destined for a multiple use, have non-return valves each or similar valves and an mechanismus to open these valve, when the container are approached one to the other for a sealed coupling.

Patents Act 1977 Examiner's report to the Comptroller under Section 17 (The Search report)

Application number GB 9525074.2

(The Search report)		
Relevant Technical Fields	Search Examiner MRS S E CHALMERS	
(i) UK Cl (Ed.O) A5R: RCJ		
(ii) Int Cl (Ed.6) A61M: 5/30, 5/315	Date of completion of Search 20 FEBRUARY 1996	
Databases (see below) (i) UK Patent Office collections of GB, EP, WO and US patent specifications.	Documents considered relevant following a search in respect of Claims:- 1-7 AND APPENDENT	
(ii) ONLINE: WPI	CLAIMS	

Categories of documents

X :	Document indicating lack of novelty or of inventive step.	P:	Document published on or after the declared priority date but before the filing date of the present application.	
Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.		E:	Patent document published on or after, but with priority date earlier than, the filing date of the present application.	
A:	Document indicating technological background and/or state of the art.	&:	Member of the same patent family; corresponding	

Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages	Relevant to claim(s)
	NONE	

Databases: The UK Patent Office database comprises classified collections of GB. EP. WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).